

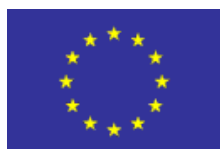
Joint Action 2013 GPSD

Joint Market Surveillance Action co-funded by the European Union
Agreement No: 2013 82 01



Final Technical Report, Toys intended for children under 3 years

Covering the period: 1 January 2014 - 30 December 2015



Co-funded by
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Disclaimer

This report arises from the Joint Market Surveillance Action on GPSD Products - JA2013, which received funding from the European Union in the framework of the 'Programme of Community Action in the field of Consumer Policy (2007-2013)'.

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Executive Summary

This report presents the activities undertaken and the results achieved in the product activity on TOYS, which formed part of the “Joint Market Surveillance Action on GPSD Products - JA2013” supported financially by the European Union under Grant Agreement No. 2013 82 01 and coordinated by PROSAFE.

Ten market surveillance authorities from 10 different EEA Countries took part in this market surveillance action. These were: Cyprus, Czech Republic, Denmark, Greece, Lithuania, Malta, Norway, Poland, Portugal and The Netherlands.

External stakeholders have been invited to attend most of the meetings for this project. ANEC, TIE, EuroCommerce, CEN and even the Toys Notified Body group actively participated in most of the meetings organised through the two-year lifetime of this project. Cooperation existed between the market surveillance authorities and these stakeholders throughout the project, with cross-sharing of positive experiences and expertise.

The focus of this activity was on TOYS INTENDED FOR CHILDREN UNDER 3 YEARS OF AGE. Various types of these toys have been chosen for sampling and testing. The type of toys is shown below:

- Activity Centres for very young children.
- Bath toys.
- Soft Books/Bath Books.
- Dolls / Figures & Accessories.
- Soft Toys.
- Teething Rings.
- Toy paints/finger paints
- Inflatable Toys.
- Soft balls.
- Rattles.
- Puzzles.
- Crayons, Plasticine, modelling clay.
- Pull along / push along toys with / without cords.
- Other Toys (painted) - wooden.
- Other Toys (painted) - metal.
- Mouth-Actuated Toys.
- Other toys.

312 economic operators were inspected as a result of this market surveillance activity on toys, out of which 9 were manufacturers, 82 were importers and around 221 were distributors. More than 1.850 different models of toys were inspected, out of which 604 samples were sent for testing. Testing mainly focused on the mechanical and physical properties of the toy, in line with certain clauses of the European Standard EN 71-1:2011+A3:2014. On the other hand, a number of samples were tested for chemical requirements, in particular, migration of certain elements in line with EN 71-3:2013+A1:2014 and also the determination of content of phthalates in such toys.

The market surveillance authorities checked the labelling requirements directly from their end, ensuring that any particular wording used to warn consumers, made use of the appropriate language according to which particular Member State these toys were being sold in. 40% of the 604 samples tested had some problems related to labelling requirements. 23% did not have the language as determined by the respective national authority. This is of particular importance to consumers who need to fully understand the information available on the toy. More detailed information can be found in section 3.3 of this report.

Additionally, the market surveillance authorities had to assess the test results, together with additional information, to come up with a **risk assessment** of each product. It is only then that the level of risk is determined on each sample, thus determining the corrective actions necessary. Figure 1 on the next page shows the overall risk levels found within various requirements focused upon:

(i) physical and mechanical requirements

Around 35% of the 265 samples tested within this category had a serious risk.

(ii) migration of certain elements

Less than 1% of the 200 samples tested within this category had a serious risk

(iii) phthalate content.

Around 12% of the 228 samples tested within this category had a serious risk.

More detailed information can be found in section 4 of this report.

Ultimately, once the risk level was determined, market surveillance authorities took action / measures to remedy any unsafe situations within their respective part of the Single Market. In some cases, the market surveillance authorities ensured that the responsible economic operator performed recalls of certain dangerous products. In other cases, a withdrawal from the market or a sales ban was enough to reduce the risk. In some cases corrective action in liaison with the responsible economic operator was necessary to further reduce the risk accordingly. More detailed information can be found on the types of measures taken within section 4 of this report.

Statistics shown in this report need to be used and interpreted with caution. The scope of such projects is not to determine the percentage level of safe products within the respective parts of the Single Market but rather to ensure that any dangerous products are completely removed as quickly as possible, through effective collaboration between market surveillance authorities and economic operators, for the ultimate benefit to consumers.

Caution!

The testing results shown above are based on products that were sampled from the markets in the participating countries by experienced market surveillance inspectors that were looking for non-compliant and potentially unsafe products. As in any routine market surveillance activity, the results represent the targeted efforts that authorities undertake to identify unsafe products. They do not give a statistically valid picture of the market situation.

The samples were tested at an accredited laboratory. The test focused on those safety requirements that have the largest impact on consumer health and safety.

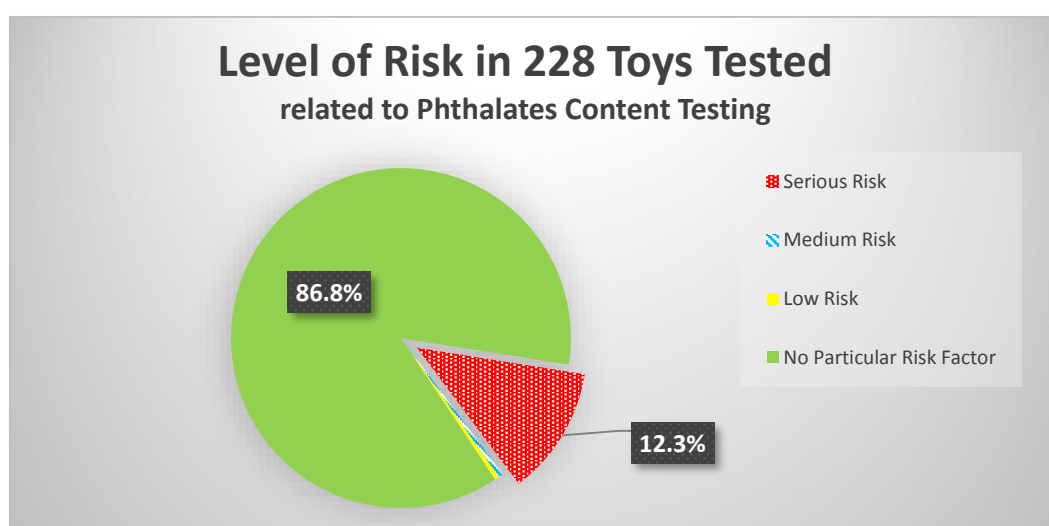
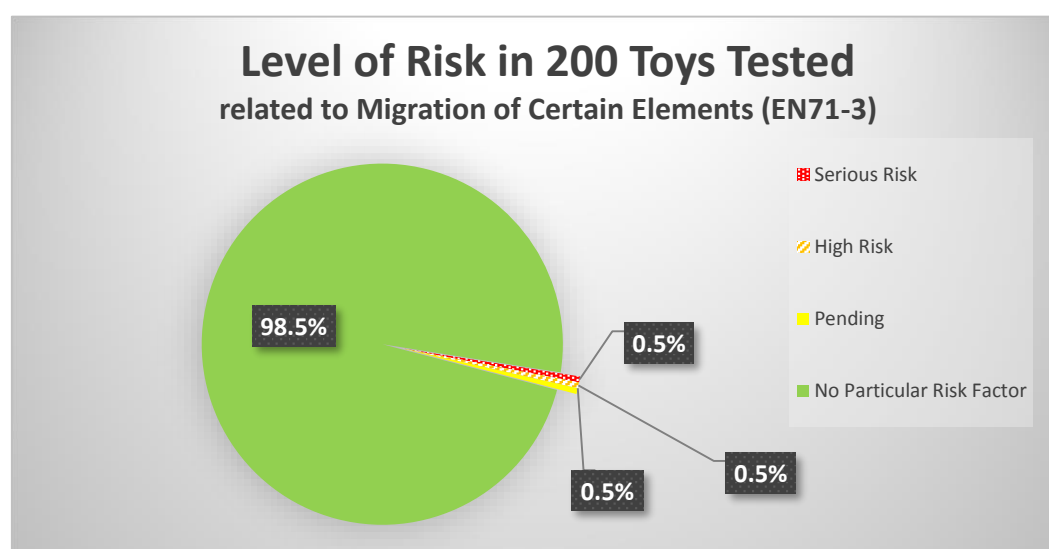
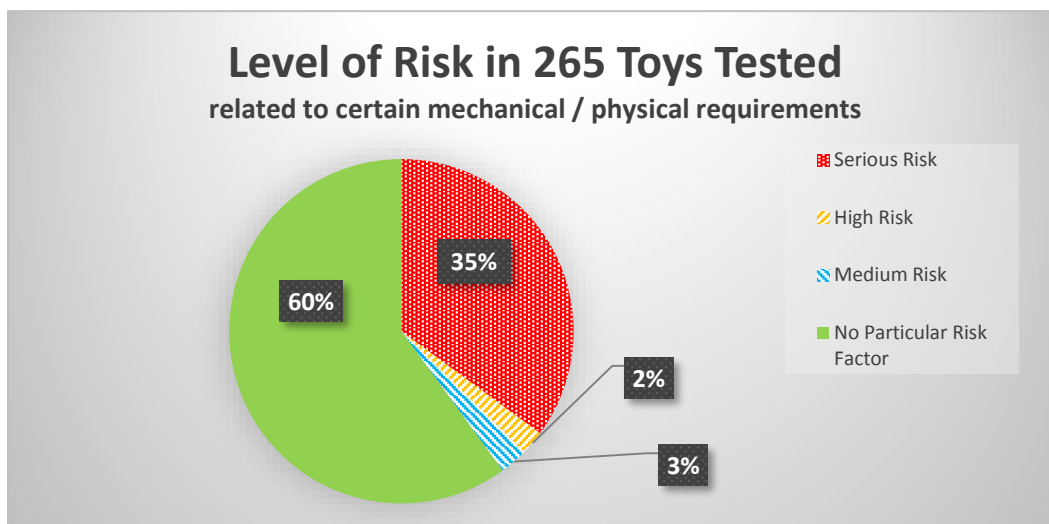


Figure 1 - Overall Risk Levels found within samples tested
(In total, 604 samples were tested, some of which were tested for more than one requirement)

Introduction

This is the final technical report related to the market surveillance activity on TOYS, being part of the Joint Market Surveillance Action on GPSD Products - JA2013. The Joint Action received funding from the European Union in the framework of the 'Programme of Community action in the field of Consumer policy (2007-2013)'.

The technical results, including the type of tests and non-compliances found within the samples that were tested by this working group, can be found in section 3.1 and 3.2. A short summary about the technical level of non-compliances is presented at the beginning of each of these two sections. Section 3.3 mainly deals with inspections related to warnings, markings and instructions for use. However, it is important to note that market surveillance authorities had to assess all this technical data and test results, together with additional information, to come up with a risk assessment of each product. It is only then that the level of risk is determined on each sample. Section 4 tries to deal with this important area of risk assessment, outlining the number of dangerous products found within the samples that were tested and also including information on measures taken by market surveillance authorities.

The importance of liaison with the European Commission, the external stakeholders, the TOY-ADCO group and other groups is highlighted within section 5 of this document. Finally, section 6 tries to give a brief summary of the lessons learnt within this project.

1 Background Information

This chapter presents a short extract of the project description. The full description can be found in the Grant Agreement [1]. The activity was part of Joint Market Surveillance Action on GPSD Products - JA2013. The activity was undertaken by PROSAFE and 10 market surveillance authorities from 10 EEA Countries took part in this activity (Cyprus, Czech Republic, Denmark, Greece, Lithuania, Malta, Norway, Poland, Portugal and The Netherlands).

The Activity Leader was Savvas Savva from the Competition and Consumer Protection Service, Ministry of Energy, Commerce Industry and Tourism in Cyprus. The Activity Leader was supported by the PROSAFE consultant, Noel Toledo.

The primary objective of this activity was to detect and remove dangerous products from the marketplace.

The product specific activities allowed the development of:

- Sharing of best practices and
- The exchange of experiences in relation to this market surveillance activity on TOYS.

The two primary activities focused on:

- Targeting the product group - *toys intended for children under 3 years of age* - examining the mechanical & physical properties and chemical aspects of a number of samples.
- Developing a priority-setting exercise on all kind of toys for future joint actions.

The project mainly followed the following activities:

- *Deciding on sampling criteria*
The Activity decided on how the Member States should carry out sampling, i.e. how many samples would be taken by each authority, when would the sampling take place, what criteria would be applied when selecting the specific samples, and how many items should be taken of each product.
- *Sample products*
The Member States would collect products according to the sampling criteria, visiting manufacturers, importers and retailers to collect products.
- *Test products at an accredited laboratory*
The Activity issued a call for tender and selected an appropriate accredited laboratory and the Member States were instructed how to send their products for testing.
- *Risk assessment*
The participants developed a common approach to risk assessment to assure that the resulting assessments were harmonised to the extent possible. The Member States then assessed the risk for the products applying the agreed approach and any relevant national conditions.
- *Follow-up on non-compliant products and exchange information on follow-up activities.*
The Member State authorities followed up towards the economic operators in their countries, i.e. consulted the economic operators on the results from the risk assessment, agreed on appropriate measures and followed-up that these were properly implemented. The resulting measures were reported to the Joint Action and shared with all participants.

There were three main phases within this project, as can be seen within the activity plan shown in Figure 2 on the next page.

Phase 1 was mainly the preparatory phase, all the aspects of the project were discussed and a project time-line was agreed upon.

Phase 2 included the process of selecting an accredited laboratory for testing and also the actual implementation, that is, the sampling and actual testing.

Phase 3, the final phase, included the collection of final statistics on risk assessment and measures taken by market surveillance authorities. This Final Technical Report has been developed within this final phase.

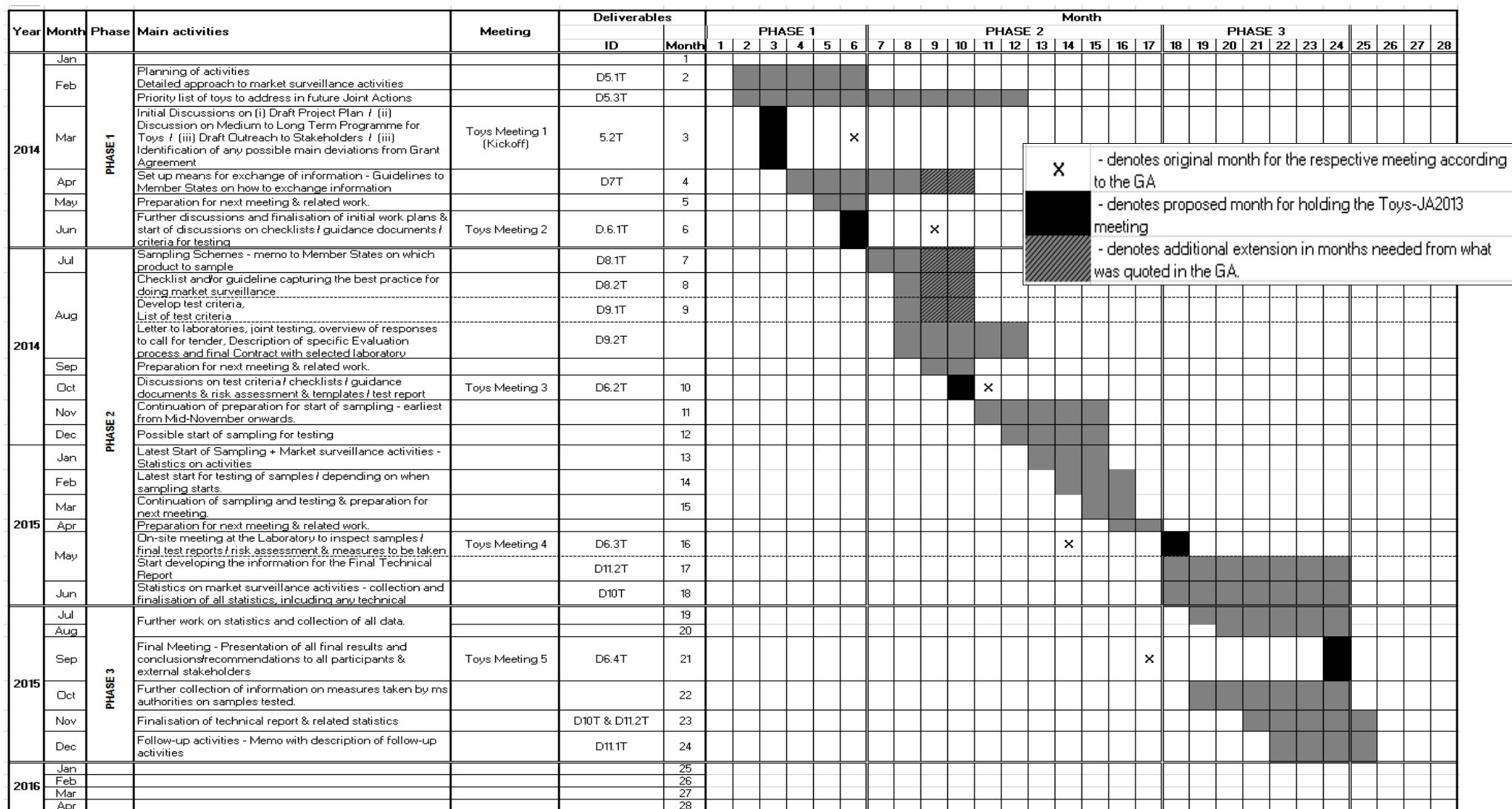


Figure 2- Project Time-line showing the three main phases

2 Setting up the Product Activity

2.1 Tendering Process for Test Laboratories

It was agreed by the working group to test a number of toys according to the physical / mechanical requirements in accordance with certain clauses of EN71-1:2011+A3:2014. Additionally, in the case of chemical requirements, the content of phthalates and the migration of elements in line with EN 71-3:2013 was also analysed.

Nine laboratories were identified and asked to tender a quote. Additionally, an email was also sent to the Secretary of the Toys Notified Body Group who in turn distributed the tender to all European Notified Body testing labs.

Seven laboratories reacted to this call for tender and in line with the stipulated deadline. After an evaluation process, the laboratory AIJU from Spain was chosen by this working group. AIJU is an accredited laboratory by ENAC (the National Accreditation Body in Spain) to perform tests according to EN 71-1:2011 + A3:2014, EN 71-3:2013+A1:2014 and the analysis of phthalates according to method CPSC-CH-C1001-09 "Determination of phthalates".

2.2 Selecting Products, Sampling

In order to perform effective sampling and be able to record statistics on information / action taken, it was important that a proper classification of toy products had to be developed.

Various types of toys intended for children under 3 years of age could have been chosen for sampling and testing through this project by the respective market surveillance authorities in line with Table 1 shown on the next page. An internal guidance document was prepared to help inspectors in their preliminary surveillance checks in the market.

Table 1 shows the number of samples tested by this working group. 604 separate toy samples have been sent for testing. However, there have been a total of 693 separate tests performed on these toys. Some were related to mechanical tests (265 in all) and others related to chemical testing (228 tests on phthalate content and 200 tests on migration of certain elements), as can be seen from this same table.

Additionally, it is worth noting that in the case of EN71-3 testing - migration of elements, the testing for each sample is only recorded once in Table 1, even though 3 different colour tests may have been carried out by the laboratory on each sample. A total of 586 different materials have been tested by the laboratory in the case of EN71-3 testing.

Additionally, inspectors were well informed in advance of the samples that needed to be focused upon. By using the checklists, the inspectors were able to better identify those samples which already showed signs of non-compliance. The target of this working group was to only try to send samples to the laboratory which already show possible signs of non-compliance. It is therefore important to note that, like any other market surveillance activity, this was NOT a random sampling exercise but rather a focused approach on particular toys which most likely are unsafe.

PRODUCT DESCRIPTION	CODE	En71-1	EN71-3	Phthalates	TOTAL TESTS CARRIED OUT	Number of Samples Tested
			Migration of certain elements			
Bath toys	BT	23	4	89	116	96
Rattles	R	53	4	12	69	57
Pull along / push along toys with / without cords	PA	38	23	1	62	56
Soft Toys	ST	27	7	20	54	39
Dolls / Figures & Accessories	DFA	8	0	29	37	30
Teething Rings	TR	11	0	23	34	26
Puzzles	P	12	12	0	24	19
Soft Books/Bath Books	B	3	0	14	17	16
Soft balls	SB	5	1	10	16	15
Crayons, Plasticine, modeling clay	CPM	1	13	0	14	13
Toy Paints / Finger Paints	TFP	0	7	0	7	7
Inflatable Toys	IT	1	0	6	7	6
Mouth Actuated Toys	MA	3	2	2	7	5
Activity Centres for very young children	AC	4	1	0	5	4
Other Toys (painted) - metal	OTM	4	10	0	14	7
Other Toys (painted) - wooden	OTW	23	103	1	127	124
Other Toys	O	49	13	21	83	84
TOTAL		265	200	228	693	604

Table 1 - Number of samples tested and the respective number of tests carried out within this project

Particular attention was given to age grading. This is important for this market surveillance activity since each authority needed to ensure that only toys intended for children under 3 years of age are sampled for testing. More stringent requirements are set on toys intended for children under 3 years of age. To further ensure that there was consistency in this process, the laboratory was also requested to perform an age grading process on the samples received including details on how this has been done and a reasoned comment in a separate document to inform the Task Leader and Task Coordinator of this project as well as the respective MS authority accordingly. Over 99% of the samples sent for testing were considered by the laboratory as toys intended for children under 3 years of age.

312 economic operators were inspected as a result of this market surveillance activity on toys, out of which 9 were manufacturers, 82 were importers and around 221 were distributors. In all, around 1.850 different models of toys were inspected, out of which 604 samples were sent for testing. Some market surveillance authorities also inspected some websites. Around 25 websites were checked, most of which were related to manufacturers or importers.

3 Testing

This section presents the aggregate results of all the tests on Toys intended for children under three years of age (TOYS) arising from the test reports of the laboratory chosen to perform this work for this joint activity. This work has been carried out following the requirements laid down in the tender conditions documents of Joint Market Surveillance Action on Toys (Grant agreement number 2013 08 01).

Two main areas where focused upon:

- (i) The physical and mechanical requirements in accordance to some of the clauses of the Standard EN 71-1:2011+A3:2014. Details can be found within section 3.1 of this document.
- (ii) The chemical requirements related to migration of heavy metals and phthalates found within a number of samples. Details can be found within section 3.2 of this document.

It is important to note that some toys were tested for both mechanical and chemical requirements whereas others were just tested for one or the other requirement. This also depended not only on the decision of authority as to whether such a sample needed to be tested for both areas but rather also dependent in some cases on the type of authority since there was one authority which was responsible solely for mechanical requirements whilst another was solely responsible for the chemical area.

NOTE: It is worth noting that although there were 10 authorities involved in this project, the authority from Denmark only participated in the mechanical testing whereas the authority from Norway only participated in chemical testing. This is because these two respective authorities are only responsible for mechanical aspects and chemical aspects respectively within their own Member State.

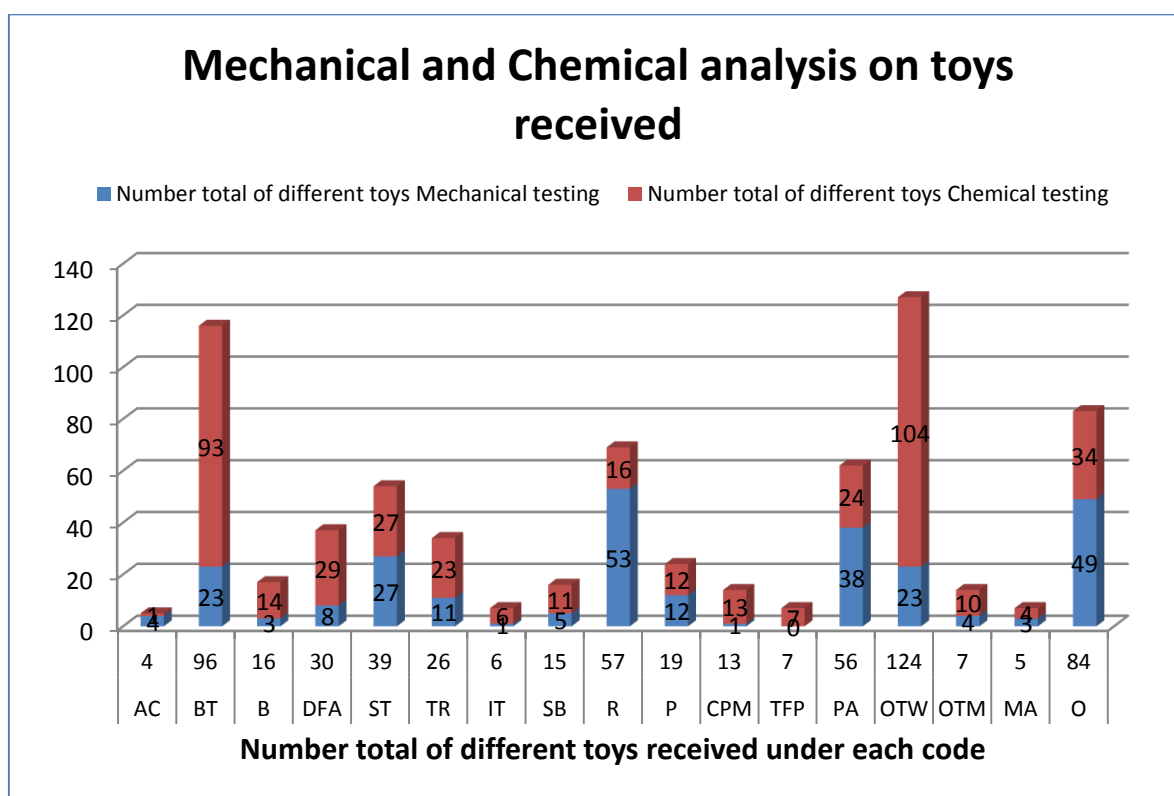


Figure 3. Distribution of total samples for mechanical and chemical analysis

Figure 3 shows how the 604 samples have been tested according to the distribution of chemical and mechanical tests and also depending on the type of toy (which is shown next to each type of toy code). The code for each type of toy can be found within Table 1 further above. Bath toys (BT), rattles (R), soft toys (ST), push-along/pull-along toys (PA), and various other type of wooden toys (OTW) constitute a total of 372 samples and 428 tests carried out on them, representing around 62% of all samples and even of all tests carried out.

3.1 Physical & Mechanical Requirements

3.1.1 Summary

A total of nine different countries have participated in this activity on mechanical and physical testing of toys. The samples were sent by the authority of each country directly to the laboratory which is accredited to perform testing according to the Standard EN 71-1:2011+A3:2014. One of the authorities did not participate directly in this particular activity since that authority itself was only responsible for chemical requirements of products, besides various other responsibilities.

The laboratory has tested a total of 265 samples according to several physical and mechanical requirements for the safety of toys intended for children under three years of age. The tests have been performed in accordance to the following clauses of the Standard EN 71-1:2011+A3:2014:

- 4.8. "Points and metallic wires".
- 4.9. "Protruding parts".
- 4.11. "Mouth-actuated toys and other toys intended to be put in the mouth".
- 5. "Toys intended for children under 36 months".
- 6. "Packaging".

Table 2 below shows the sixteen types of toys that have been tested for mechanical & physical requirements. The number of tests performed for each product type can be seen within this table.

TYPE OF TOY	NUMBER OF SAMPLES
Rattles (R)	53
Pull along / push along toys with / without cords (PA)	38
Soft Toys (ST)	27
Bath toys (BT)	23
Puzzles (P)	12
Teething Rings (TR)	11
Dolls / Figures & Accessories (DFA)	8
Soft balls (SB)	5
Activity Centres for very young children (AC)	4
Mouth-Actuated Toys (MA)	3
Soft Books / Bath Books (B)	3
Crayons, Plasticine, modelling clay (CPM)	1
Inflatable Toys (IT)	1
Other Toys (painted) - metal (OTM)	4
Other Toys (painted) - wooden (OTW)	23
Other Toys (O)	49
TOTAL	265

Table 2. Number of Tests performed for each Product Type (Mechanical & Physical Requirements)

These samples were tested at the respective chosen laboratory according to the physical-mechanical requirements mentioned. **123 (46,4 %) of the 265 samples tested at this laboratory did not meet the requirements** of respective clauses. Section 3.1 includes the final results of the mechanical and physical tests performed and a compilation of statistics taking into account the non-conformities found and the characteristics of the samples, for example, types of samples and others.

3.1.2 Test Procedure

Tests on toys intended for children under 3 years of age were performed according to Clauses 4.8, 4.9, 4.11, 5 and 6 of European standard EN 71-1:2011+A3:2014 “Safety of toys. Mechanical and Physical Properties”.

Before the performance of the tests, the samples were assembled according to the instructions for use when necessary. Most samples were provided ready for use by children and no assembly was required by the laboratory. Photographs of the samples as received by the laboratory, as well as of the toy itself, were taken to include in the test report. Additionally, when it was considered that it was necessary to better understand a non-conformity after a test, photographs of the toy parts affected were taken.

Clause 7 “Warnings, markings and instructions for use” of EN 71-1:2011+A3:2014 was not included in the tests requested by the laboratory (this was done directly by the respective market surveillance authorities). It should be noted that the information on the existing marking has been considered by the laboratory only when it has been relevant for the proper performance of these tests.

During the test procedure, if a toy failed a requirement of clause 6 of EN 71-1:2011+A3:2014, it was assessed under the previous version EN 71-1:2011 to confirm whether it met the requirements of this standard. This was mainly to help market surveillance authorities determine what action will be taken from their end, since, although any market surveillance authority may be able to take action on any dangerous element within any toy, the information on the level of compliance to the respective standards and the point in time when the respective sample was placed on the market, could further assist market surveillance authorities to decide on what type of action and measures will be taken from their end.

Additionally, if a failure occurred on a toy, the testing procedure continued unless the failure was so destructive that all further testing was impossible. Once the tests were finished, the laboratory prepared one test report for each sample according to Clauses 4.8, 4.9, 4.11, 5 and 6 of European standard EN 71-1:2011+A3:2014 “Safety of toys. Mechanical and Physical Properties”.

The respective individual test reports included the results obtained from testing the sample, and indicating in each case the non-compliances and including different pictures of these non-compliances, as well as comments or any other relevant clarifications.

It is worth noting that there were three samples from the same Member State whereby after more information was available to the respective authority, a decision was taken to also re-classify these samples as having a risk:

- In the first case, the respective market surveillance authority was approached directly by the manufacturer who told them that they will be removing the product (a wooden toy) due to small parts which actually were not accessible but only released by a torque or tension test. It could be that the initial sample sent for testing did not have such a problem and therefore did not show this non-compliance. This was classified by the authority as “serious risk”.
- In the second case, after more information was available to the respective authority, the sample was tested further by a separate laboratory chosen by the market surveillance authority. This resulted that small parts were released when the toy was dry as per clause 5.1 of the respective standard. This was also classified by the authority as “serious risk”.
- The third and final case was related to a small part attached to the toy as part of the packaging was released with a force less than 90 N. According to the authority, it is foreseeable use that parents do not discover the small part and thus do not remove it before giving the toy to a child. Action was taken by the authority to remove these samples from the market. This was classified by the authority as “medium risk”.

Although these three cases are not included as non-compliant in the respective overall test results shown further below since they show the results of the laboratory itself, they are however included within the final risk assessment and measures taken by the authorities in section 4 of this document.

3.1.3 Overall Results

It can be concluded that 123 (46,4 %) out of the 265 samples tested by the laboratory did not meet the requirements of requested Clauses 4.8, 4.9, 4.11, 5 and 6 of European standard EN 71-1:2011+A3:2014 “Safety of toys. Mechanical and Physical Properties” (see figure 4).

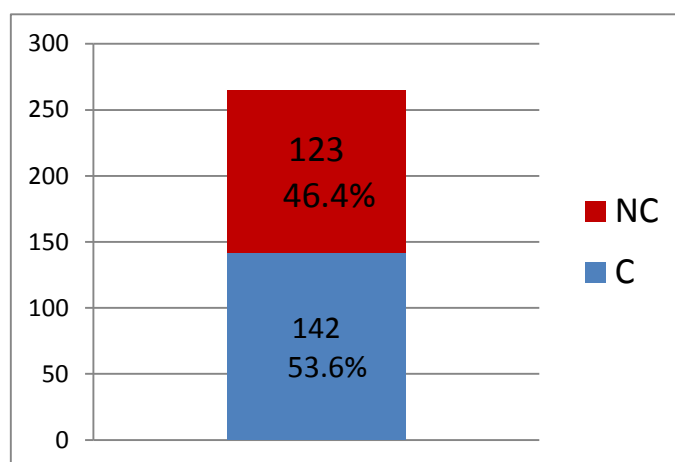


Figure 4. Overall results of the samples tested

Given that the samples were classified by the market surveillance authorities according to different types of toys, Figure 5 below shows the level of non-compliance found within each product group. Reference can be made to Table 1 for the meaning of each abbreviation shown in the chart below

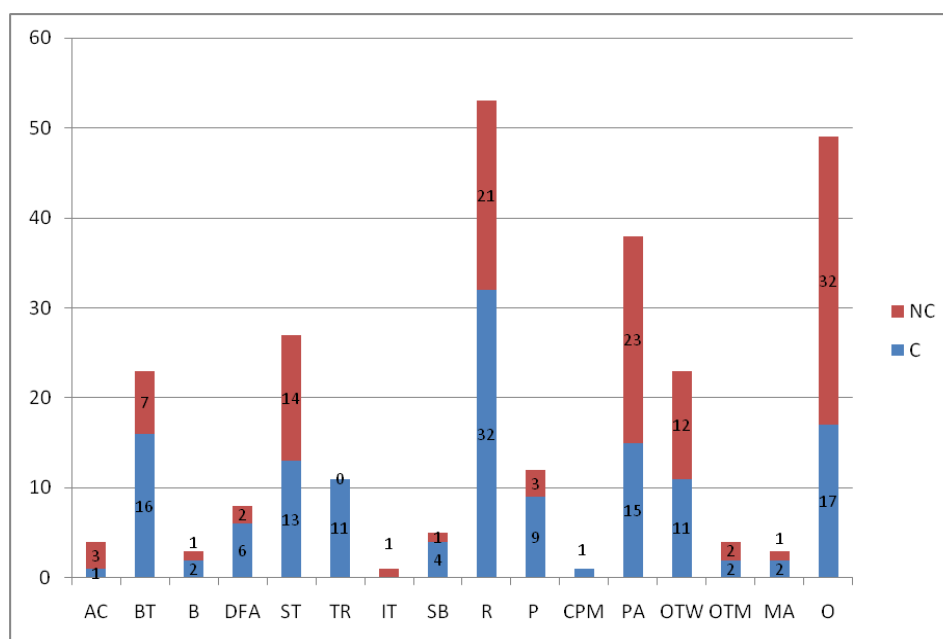


Figure 5. Non-complying samples according to the type of toy

Figure 6 below shows the same non-compliances but in percentage levels. However, it is important to note that each product group did not have the same number of toys. Therefore, one cannot compare directly these groups. For example, 100 % of the samples in the case of Inflatable Toys (IT) did not meet the requirements, but only one sample was tested.

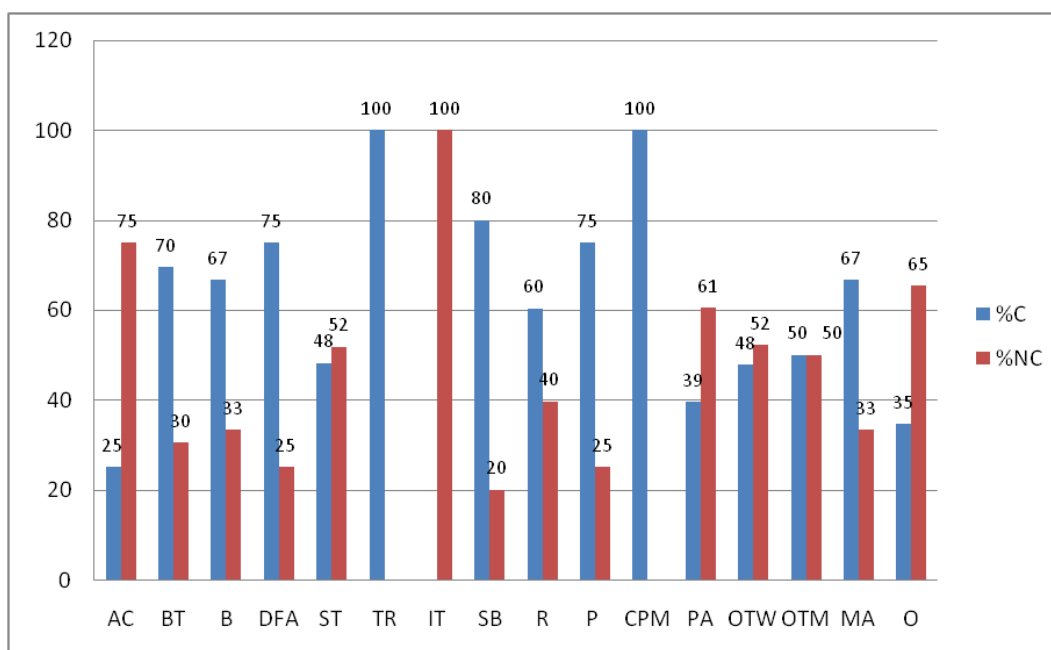


Figure 6. % of non-complying samples according to the type of toy

The same data is also shown in Table 3. This again includes the percentage of samples that did not meet the requirements according to the type of toy.

TYPE OF TOY	AC	BT	B	DFA	ST	TR	IT	SB	R	P	CPM	PA	OTW	OTM	MA	O
%NC	75,0	30,4	33,3	25,0	51,9	0,0	100,0	20,0	39,6	25,0	0,0	60,5	52,2	50,0	33,3	65,3

Table 3. % of non-compliant samples according to the type of toy

3.1.4 Results of the tests

This section of the report includes these results in detail, along with some statistics according to different factors.

Clause	Title	Non-compliances	% Non-compliances
4.8	Points and metallic wires	19	11,6%
4.9	Protruding parts	0	0,0
4.11	Mouth-actuated toys and other toys intended to be put in the mouth	1	0,6%
5	Toys intended for children under 36 months	117	71,3%
6	Packaging	27	16,5%

Table 4. Non-compliances found according to Clauses 4.8, 4.9, 4.11, 5 and 6 of European standard EN 71-1:2011+A3:2014

In order to simplify the interpretation of results and for statistical purposes, test results showing a “pass” or “not applicable” have been included in the same category as a “pass”.

, Table 4 presents the non-compliances for physical-mechanical properties found according to the different clauses of this standard. Figure 7 below shows a graphical display of the same percentage non-

compliances related to physical-mechanical tests performed. It may be worth noting that the biggest number of non-compliances appear in clause 5 - 'Toys intended for children under 36 months'.

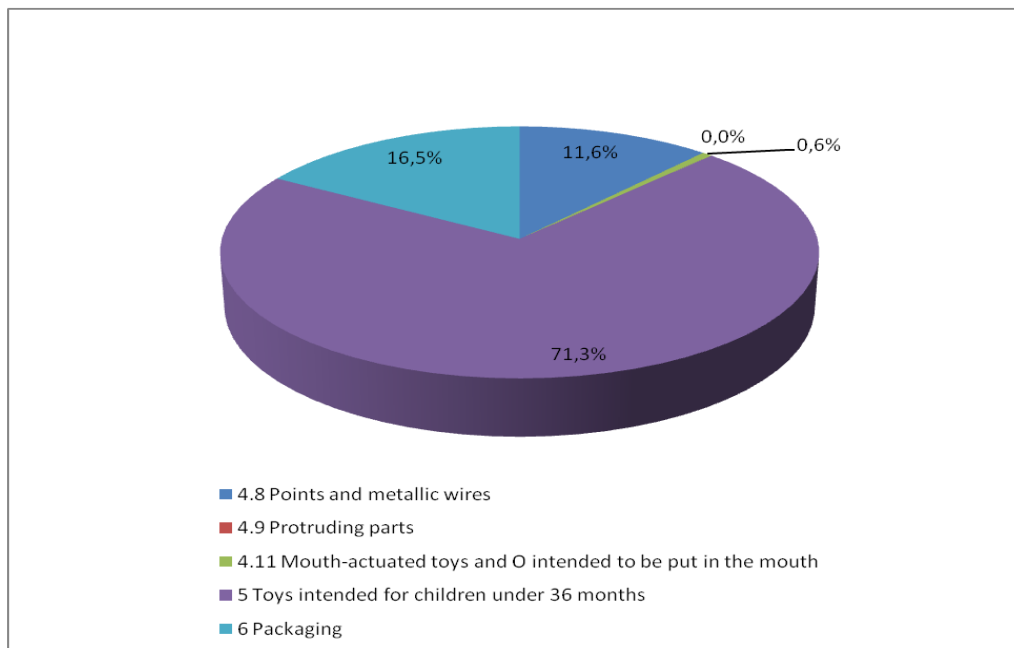


Figure 7. Distribution of non-compliances

Other clauses that had high levels of non-compliances were clause 6 - 'Packaging' and clause 4.8 - 'Points and metallic wires' with a percentage non-compliance of 16,5% and 11,6% respectively.

There were no non-compliances related to clause 4.9 'Protruding parts'.

Overall Conclusions

The results obtained and conclusions from each physical-mechanical test performed by the laboratory are explained below.

Clause 4.8 'Points and metallic wires'

In this clause of the standard metallic wires and accessible points were evaluated. The toys have been assessed as to whether there was the presence of sharp points before and after the applicable tests. Comments appear below.

RESULTS: 19 of 265 samples tested did not meet the requirements mentioned above. Different types of failures have been detected, especially after impact test (see figure 8, 9, 10 and 11). None of the samples presented sharp point as received.

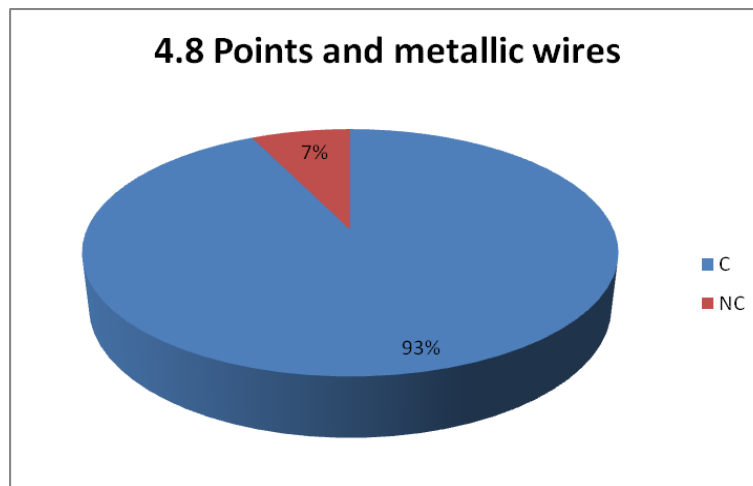


Figure 8. Points and metallic wires.

In most of the cases, sharp points appeared after 8.7 Impact test. As a consequence, the toy broke down into pieces and originated these sharp points.



Figure 9. Sharp points after 8.7 Impact test

In 3 samples, the inner mechanism with sharp points remains accessible after 8.4.2 Tension test (see figure 10).

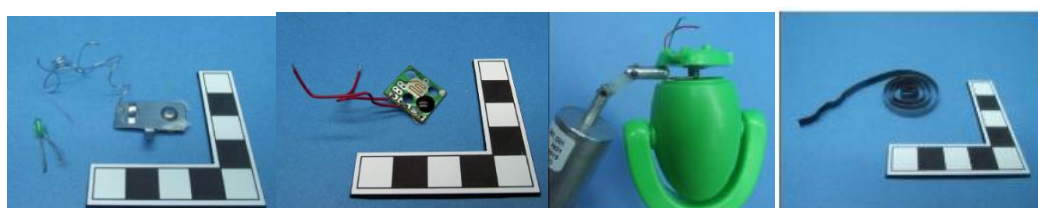


Figure 10. Sharp points after 8.4.2 Tension test 8.4.2

In one of the samples, the hook that the toy included detached during 8.3 Torque test and originated a sharp point (see figure 11).



Figure 11. Sharp points after torque test 8.3

Given the type of toy, the non-compliances were found in the toys detailed in figure 12 (mainly in rattles, other toys and pull along/push along toys with/without cords).

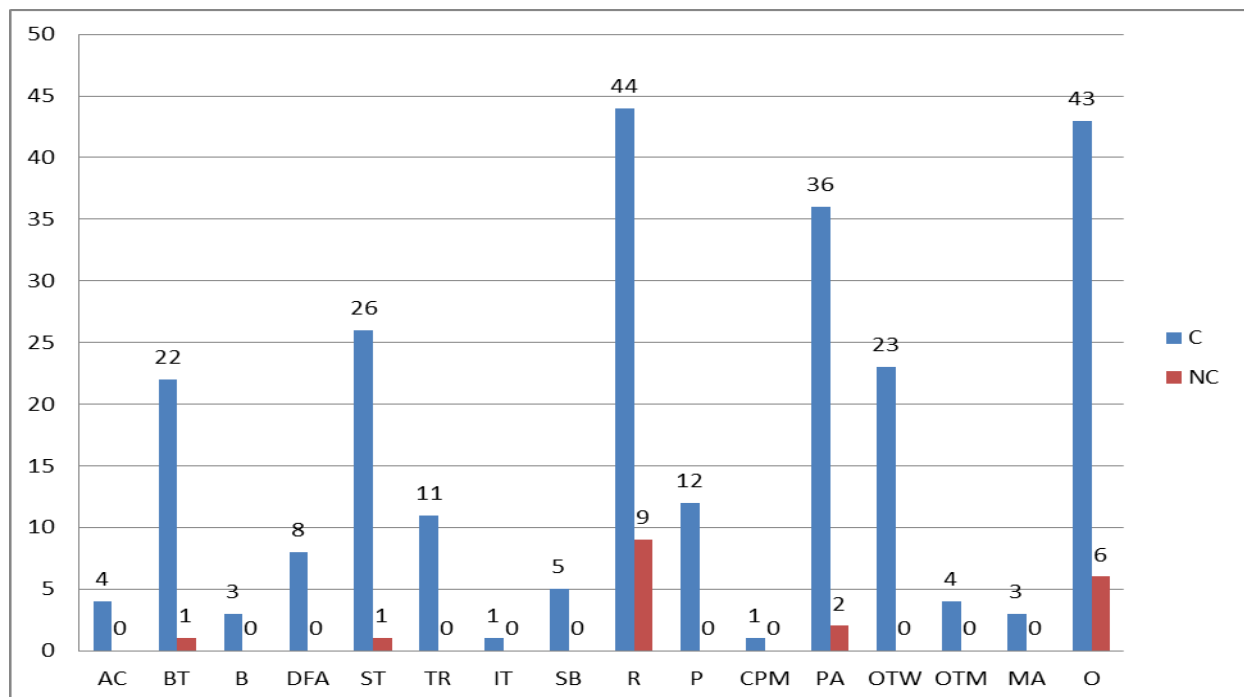


Figure 12. Non-compliances in sharp points according to the type of the sample

Clause 4.9 'Protruding parts'

According to this clause, tubes and rigid components in the form of projections which constitute a puncture hazard to a child shall be protected and tested according to 8.4.2.3 (tension test, protective components).

RESULTS: All the samples tested as a 'PASS' for this requirement. No non-complying samples according to this clause were found.

Clause 4.11 'Mouth-actuated toys and other toys intended to be put in the mouth'

The requirements of this clause in general are intended to address the choking hazard associated with unintentional inhalation of toys intended to be put in the mouth, mouth-actuated toys or detachable and removable components of these toys.

To ascertain that mouthpieces do not become loose if they become wet after prolonged use in the mouth, they are subjected to a soaking test before being subjected to the torque and tension tests.

RESULTS: Of the 3 samples received within the mouth-actuated toys category, one sample did not meet the requirements as, after the soaking test, the plasticized paper stickers detached and generated small parts (see figures 13 and 14).

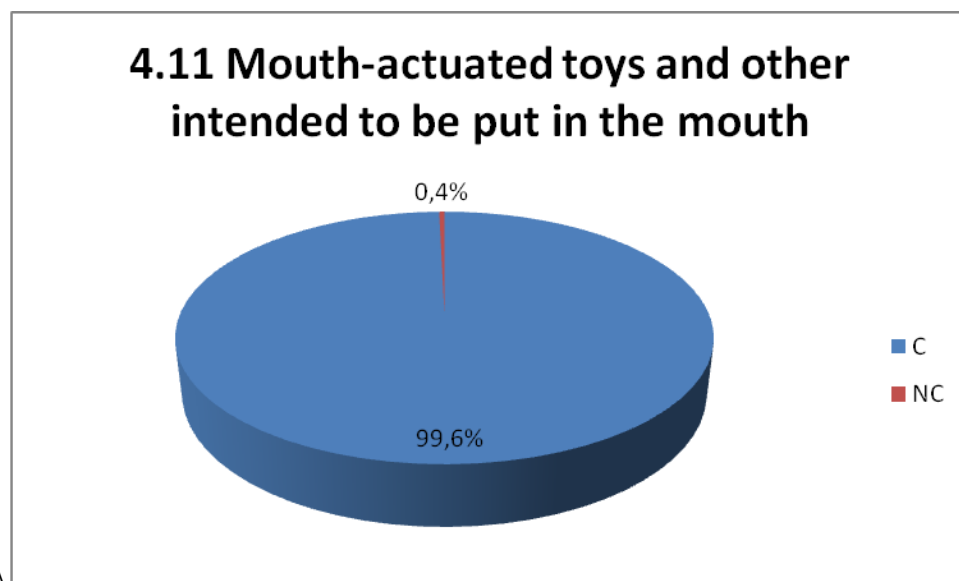


Figure 13. Non-compliances in mouth-actuated toys and other toys intended to be put in the mouth



Figure 14. Small parts in mouth-actuated toys and other toys intended to be put in the mouth

Clause 5 'Toys intended for children under 36 months'

Toys intended for children under 36 months shall in addition to relevant requirements of Clause 4 conform to the requirements of Clause 5, where applicable.

RESULTS: 117 (44,2%) of 265 tested samples failed clause 5 (see figures 15 and 16).

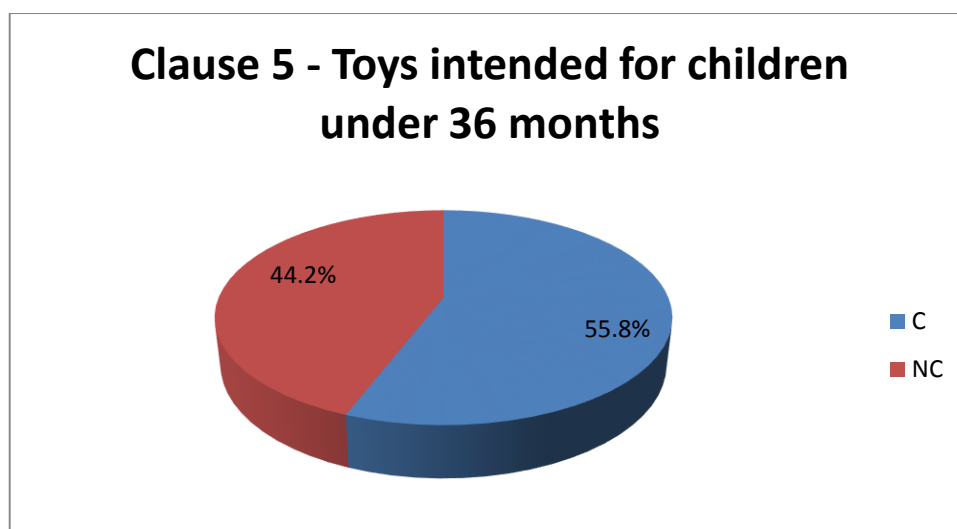


Figure 15. Results on clause 5. “Toys intended for children under 36 months”

Table 5 includes in detail the results obtained during clause 5 ‘Toys intended for children under 36 months’. Figure 16 includes the non-compliances found within the tested samples.

Clause	Title	Non-compliances	% Non-compliances
5.1	General requirements (small parts)	103	55,1%
5.2	Soft-filled toys and soft-filled parts of a toy	11	5,9%
5.3	Plastic sheeting	0	0,0
5.4	Cords, chains and electrical cables in toys	20	10,7%
5.5	Liquid-filled toys	0	0,0
5.6	Speed limitation of electrically-driven ride-on toys	0	0,0
5.7	Glass and porcelain	0	0,0
5.8	Shape and size of certain toys	24	12,8%
5.9	Toys comprising monofilament fibres	0	0,0
5.10	Small balls	26	13,9%
5.11	Play figures	0	0,0
5.12	Hemispheric-shaped toys	1	0,5%
5.13	Suction cups	2	1,1%
5.14	Straps intended to be worn fully or partially around the neck	0	0,0

Table 5. Non-compliances found according to Clause 5

More than half of the non-compliances according to this clause belong to clause 5.1 “General requirements”, in particular to tension and impact tests. The laboratory also found a number of non-complying samples according to the requirements included in clauses 5.10 “Small balls”, 5.8 “Shape and size of certain toys”, 5.4 “Cords, chains and electrical cables in toys” and 5.2 “Soft-filled toys and soft-filled parts of a toy”.

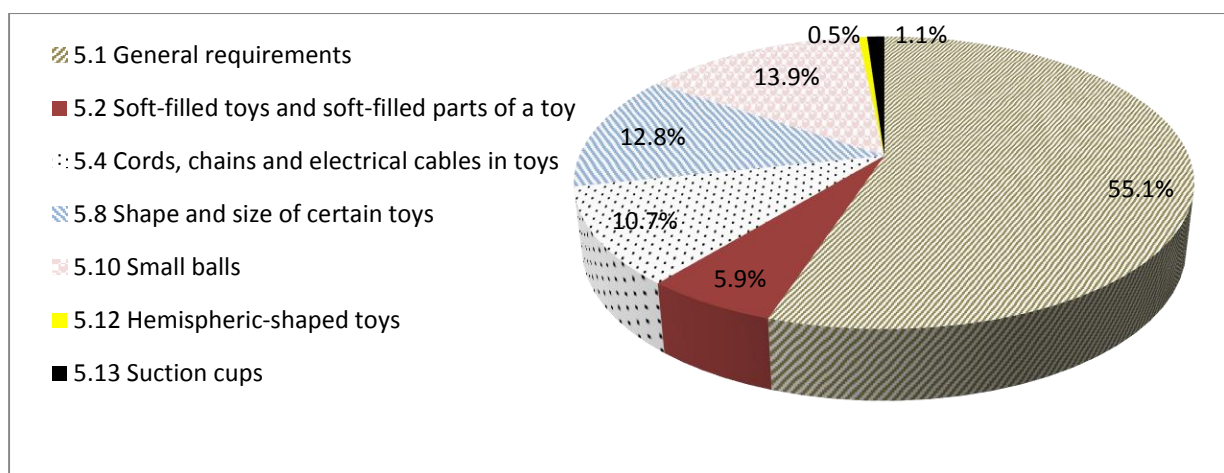


Figure 16 Distribution of non-compliances according to Clause 5

Figure 17 shows the percentage non-complying samples within each of the toy product groups. Refer to Table 1 for an explanation of what each abbreviation stands for.

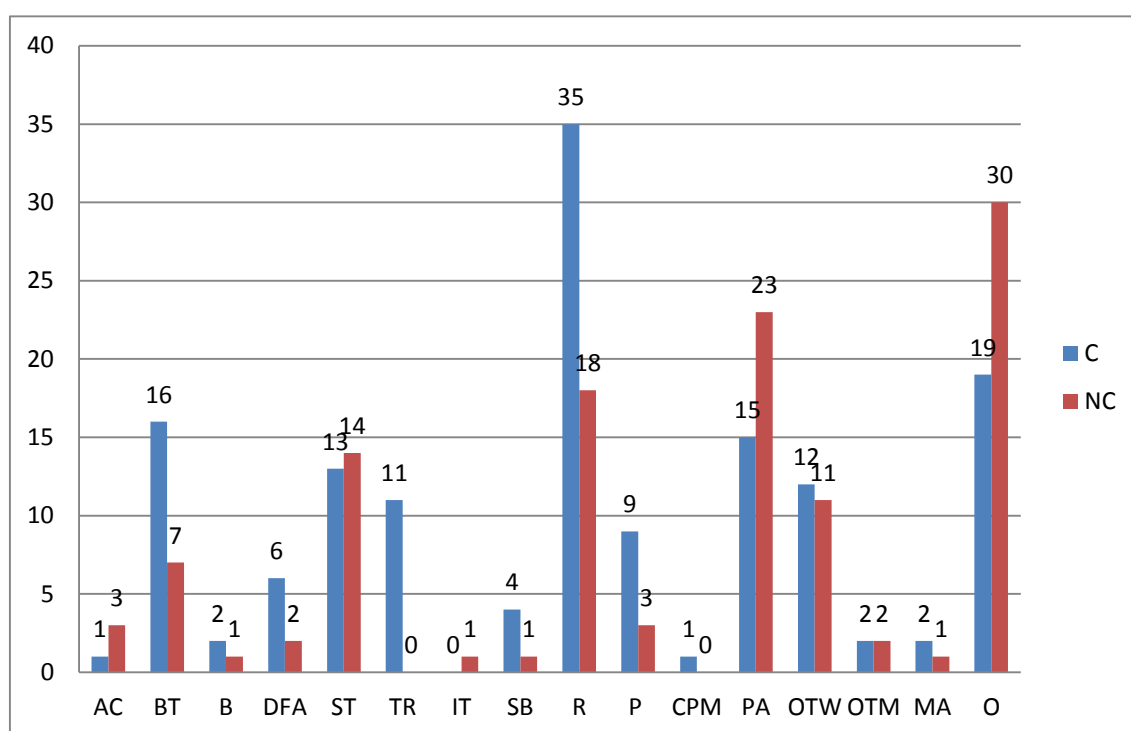


Figure 17. % of non-complying samples according to the type of toy in clause 5

Clause 5.1 General requirements

These requirements are intended to address the hazard associated with insufficient strength and durability of young children's toys, which are generally subject to considerable wear and tear. They are intended to address the hazards associated with small parts, capable of causing choking, being inhaled or swallowed, as well as hazards in connection with sharp edges, sharp points and springs, which jam fingers, etc.

RESULTS: 103 samples (38,9 %) of the 265 tested samples failed this requirement. 7 of the 103 samples presented small parts as received (see figure 18).



Figure 18. Small parts in toys as received

In 6 samples the small parts were plastic stickers (see figure 19).



Figure 19. Examples of plastic stickers that are small parts

Other examples that have caused small parts after other tests as tension, torque, impact, etc are shown in figure 20.





Figure 20. Examples of other small parts

Clause 5.2 Soft-filled toys and soft-filled parts of a toy

The requirements of this clause are intended to address the hazards related to objects that can cause cuts or lacerations if accessible, or choking if inhaled, or harm by ingestion. Therefore, it must be ensured that a child cannot get access to small parts should a seam break open on a soft-filled toy or a soft-filled part of a toy containing small parts or a containing a filling that could potentially release a small part.

Additionally, requirement in 5.2 covers soft-filled toys and soft-filled parts of a toy, containing fibrous filling materials and no small parts.

RESULTS: 11 samples (4,2%) of the 265 tested samples failed this requirement.

It is worth noting that a few samples received at the laboratory had open seams before test 8.4.2.2 (see figure 21).



Figure 21 Sample with open seam & fibrous filling material easily accessible

In the rest of the samples, after the tension test on seams and using a maximum force of 70 N, these seams opened and left the inner stuffing accessible (see figure 22).



Figure 22 Detail of samples non-complying with clause 5.2

One of the samples included an inner seam that was open before the tests (as received), but other seams also opened during the tension test (see figure 23).



Figure 23 Detail of samples non-complying with clause 5.2

Plastic Sheeting

These requirements are intended to address the hazards associated with plastic sheeting or plastic decals on toys. None of the samples have been tested according to this clause since it was found to be not applicable.

Clause 5.4 Cords, chains and electrical cables in toys

These requirements are intended to prevent children from being strangled by cords or chains on toys. They also address the risk of the child being entangled by a self-retracting cord.

RESULTS: 20 samples (7,5%) of the 265 tested samples failed this requirement.

The reason why most of the samples did not meet this clause was the length of the cord (longer than required). However, in some cases the reason of the non-compliance was the thickness, lower than required by the standard (1.5 mm) (see figure 24).



Figure 24. Detail of samples non-complying with clause 5.4

One of the 22 non-complying samples did not meet the requirement of clause 5.4.e about force of self-retraction mechanisms for cords in toys (see figure 25).



Figure 25 Non-complying sample with clause 5.4.e

Clause 5.5 Liquid-filled toys

These requirements are intended to address the hazards associated with punctured teething rings and similar products where the child might come into contact with liquids that are contaminated or become contaminated due to a puncture.

RESULTS: 11 samples were received within the teething rings category, but only 7 samples were liquid-filled teething rings. All the samples meet the requirements

Clause 5.6 Speed limitation of electrically-driven ride-on toys

None of the samples have been tested according to this clause since the samples were not applicable.

Clause 5.7 Glass and porcelain

None of the samples have been tested according to this clause since the samples were not applicable.

Clause 5.8 Shape and size of certain toys

These requirements are intended to address hazards associated with toys intended for children who are too young to sit up unaided, and that could cause impaction.

RESULTS: 24 samples (9,1 %) of the 265 tested samples failed this requirement.

Figure 26 shows some examples of failure in test 8.16 (geometric shape of certain toys).



Figure 26. Detail of samples non-complying with clause 5.8

Clause 5.9 Toys comprising monofilament fibers

None of the samples have been tested according to this clause since the samples were not applicable.

Clause 5.10 Small balls

Small parts are released during the drop and impact tests (see figure 27).

RESULTS: 26 samples (9,8 %) of the 265 tested samples failed this requirement.

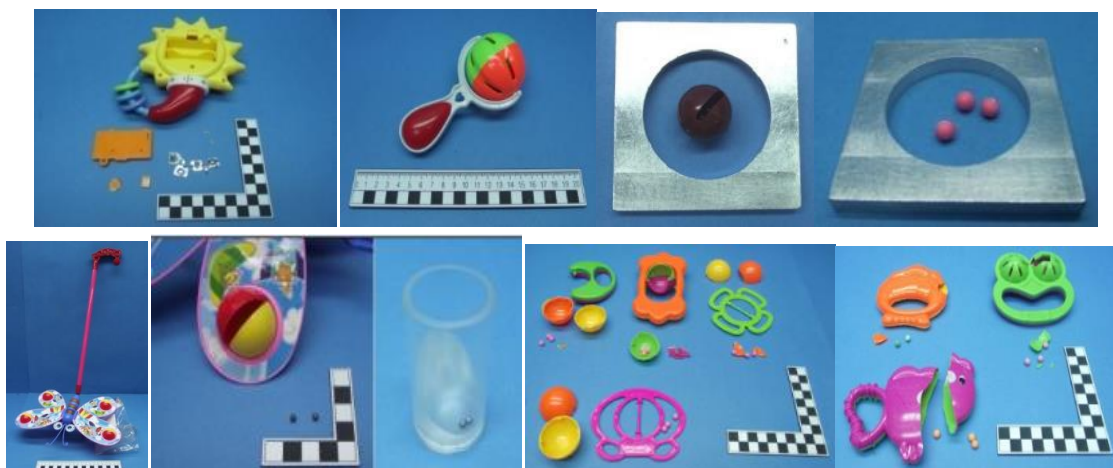


Figure 27. Detail of samples non-complying with clause 5.10 after drop and impact tests

In some cases, some balls were released during drop and impact tests, and during the tension test these balls opened and released smaller balls (see figure 28).



Figure 28. Examples of samples non-complying with clause 5.10.

Small balls have been released also during the tension test (see figure 29).



Figure 29. Detail of samples non-complying with clause 5.10 after tension tests

Additional samples have been found including small balls attached to a cord (see figure 30).



Figure 30. Examples of small balls attached to a cord

Only on sample included a small ball as received (see figure 31).

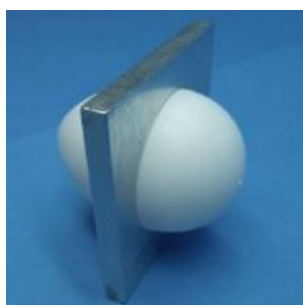


Figure 31. Small ball.

Clause 5.11 Play figures

None of the samples have been tested according to this clause since the samples were not applicable.

Clause 5.12 Hemispheric-shaped toys

Only one case failed this clause (see figure 32).

The parasol of the toy table had an external diameter of 79.66 mm. The volume was 52.5 ml. The inner diameter was between 64 mm and 102 mm and the depth greater than 13 mm.



Figure 32. Hemispheric-shaped toy.

Clause 5.13 Suction cups

RESULTS: 2 samples (0,8%) of the 265 tested samples failed this requirement (see figure 33).

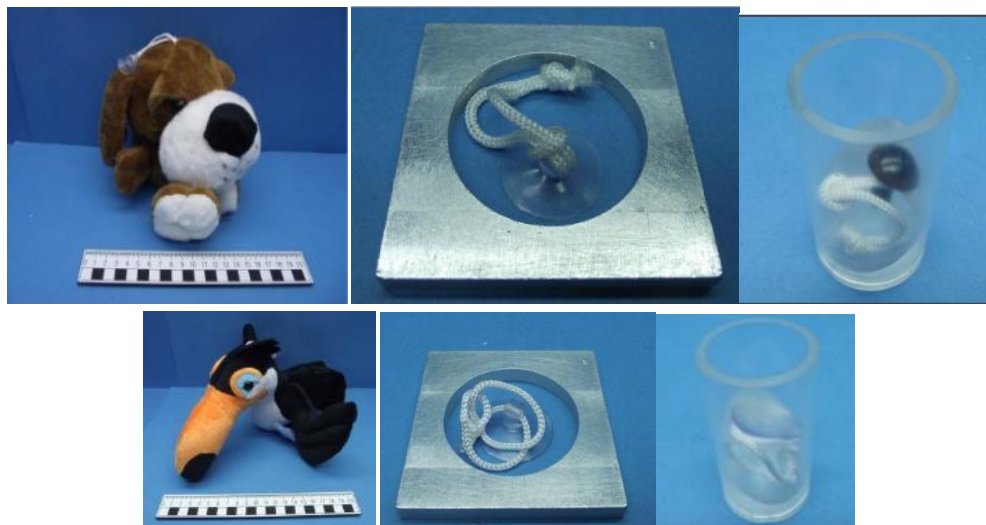


Figure 33. Suction cups.

Clause 5.14 Straps intended to be worn fully or partially around the neck

None of the samples have been tested according to this clause since the samples were not applicable.

Clause 6 'Packaging'

The requirements on the packaging of the toys were evaluated, such as:

- Average sheet.
- Presence of strings or cords as a means of closing bags made of flexible plastics with an opening perimeter greater than 380 mm.
- Small balls in packaging and packaging components.
- Hemispheric-shaped toys in packaging.

RESULTS: 27 of the 265 samples tested did not meet this requirement (see figure 34)

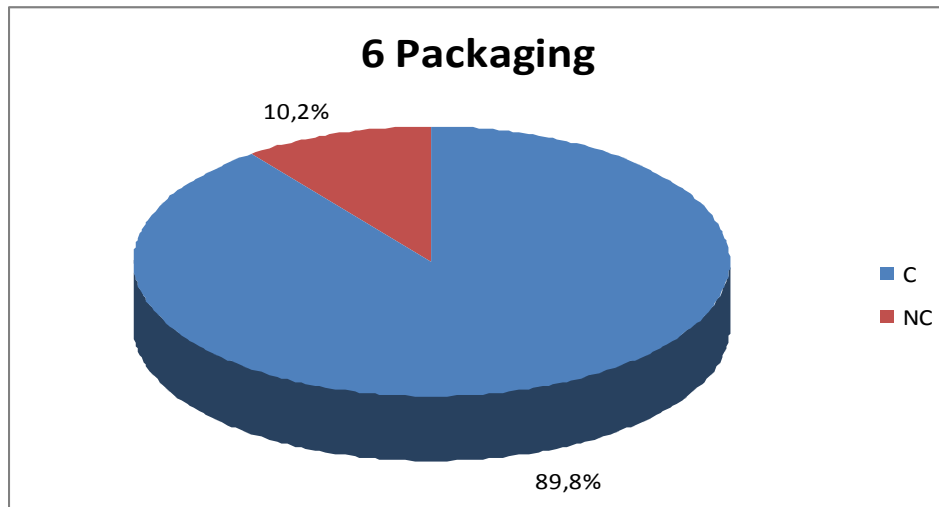


Figure 34. Results of packaging

The non-conformities found in the different types of toys are represented in figure 35.

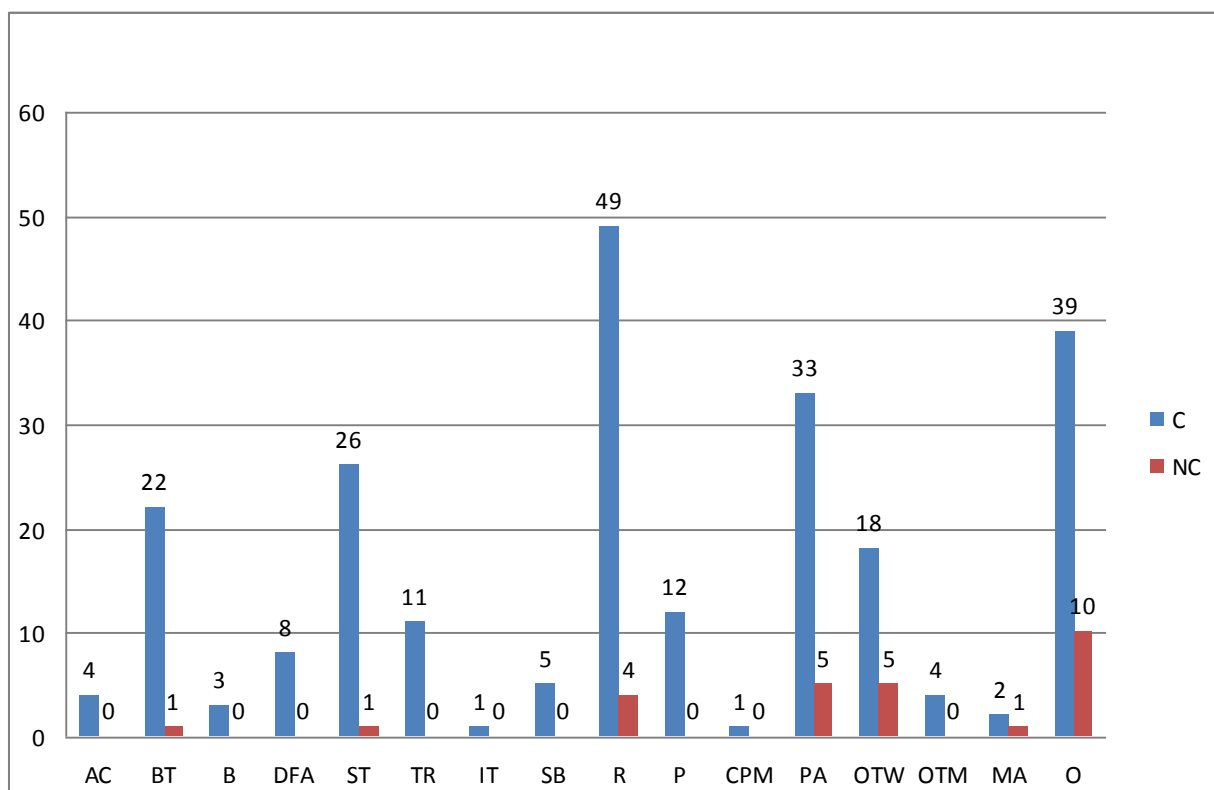


Figure 35. Non-compliances in packaging according to the type of the sample

The 27 samples that failed a requirement included in Clause 6 of standard EN 71-1:2011+A3:2014 were assessed under the previous version EN 71-1:2011 to confirm whether they met the requirements of this standard too. 3 of the 27 samples complied with the previous version of the standard. The results are shown in figure 36.

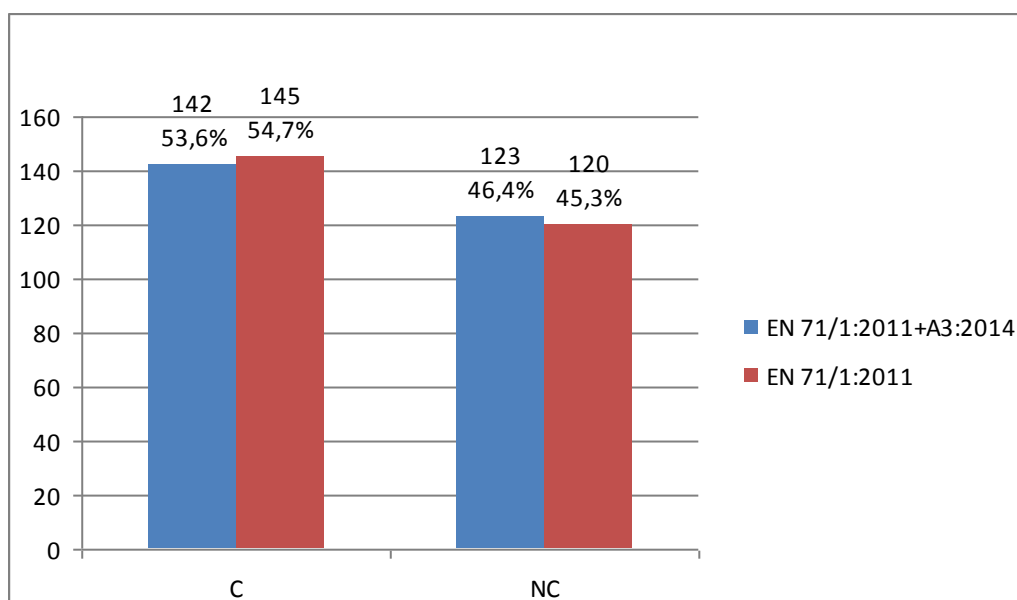


Figure 36. Comparative results between the two versions of standard EN 71/1

According standard EN 71-1:2011 an average sheet thickness of 0.038mm or more was required when the plastic bags have an opening perimeter greater of 380mm. With the enforcement of the amendment EN 71-1:2011+A3:2014, this exigency was extended to the plastic bags of an area superior to 100mmX100mm.

It may be also worth noting that out of the 265 tested for mechanical requirements, 33 of these samples did not have any label information about the responsible economic operator. These toys did not have any information whatsoever about the manufacturer or the importer.

From the test results, it is evident that 76% out of these 33 samples did not comply with the respective mechanical requirements.

It may be worth discussing this further with Customs authorities in order to possibly focus more on such toys with no label information. This would possibly have a two-fold effect:

- (i) To reduce unsafe samples on the market by having the respective market surveillance authorities test such products
- (ii) To better educate importers that such toys cannot be imported within the European Economic Area without such information.

3.2 Chemical Requirements

3.2.1 Summary

One important hazard associated with toys is the presence of dangerous chemicals. Table 6 shows the injury associated with each hazard.

Product hazard	Injury
Presence of toxic substances	Intoxication
Presence of sensitising substances	Sensitisation, allergic reaction
Presence of CMR substances (<i>that is, substances which are carcinogenic, mutagenic or toxic for reproduction</i>)	Cancer, mutation, reproductive toxicity

Table 6: Main chemical hazards in toys

The tests on toys are performed in accordance to the general requirements and test methods specified in EN 71-3: 2013 for the analysis of the migration of elements. Related to phthalates, requirements are regulated under REACH; however, at this moment there are several methods available. For the purposes of this market surveillance activity, the laboratory decided to apply method CPSC-CH-C1001-09, based on the analysis of the total content of such substances.

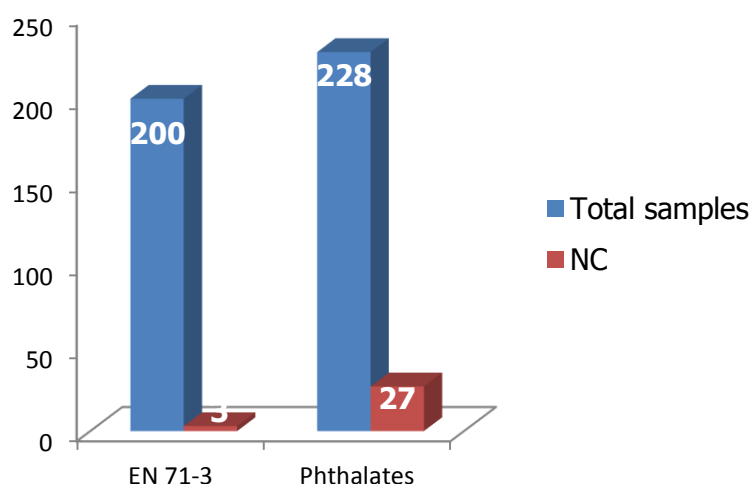


Figure 37: Overall number of chemical non-compliances

Figure 37 shows the overall non-compliances found in the samples according to the analysis performed. It is worth noting that although the total number of toys analysed for the migration of elements is 200, the overall number of materials analysed was 586.

Of the 200 samples tested, 3 samples did not meet the requirements of European standard EN 71-3:2013+A1:2014. According with the classification of the toy, non-compliances of migration of elements are from 2 toys of the CPM category and 1 toy of OTW.

Of the 228 toys analysed, 27 did not meet the requirements of REACH related to phthalates. Further details are given within the various upcoming sub-sections of section 3.2.

Table 7 & 8 below show the various type of toys that have been tested for migration of certain elements according to EN 71-3 and for phthalate content. The number of tests performed for each product type can be seen within these tables.

Type of Toy	Migration of certain elements (EN 71-3 Tests)
Pull along / push along toys with / without cords (PA)	23
Crayons, Plasticine, modelling clay (CPM)	13
Puzzles (P)	12
Soft Toys (ST)	7
Toy Paints / Finger Paints	7
Rattles (R)	4
Bath toys (BT)	4
Mouth-Actuated Toys (MA)	2
Soft balls (SB)	1
Activity Centres for very young children (AC)	1
Other Toys (painted) - metal (OTM)	10
Other Toys (painted) - wooden (OTW)	103
Other Toys (O)	13
TOTAL	200

Table 7. Number of Tests performed for each Product Type (EN 71-3 Testing)

Type of Toy	Phthalate Tests
Bath toys (BT)	89
Dolls / Figures & Accessories (DFA)	29
Teething Rings (TR)	23
Soft Toys (ST)	20
Soft Books / Bath Books (B)	14
Rattles (R)	12
Soft balls (SB)	10
Inflatable Toys (IT)	6
Mouth-Actuated Toys (MA)	2
Pull along / push along toys with / without cords (PA)	1
Other Toys (painted) - wooden (OTW)	1
Other Toys (O)	21
TOTAL	228

Table 8. Number of Tests performed for each Product Type (Phthalate Testing)

3.2.2 Chemical Test Procedure

Chemical tests on toys, intended for children under 3 years of age, were performed according to European standard EN 71-3:2013+A1:2014 “Safety of toys. Migration of certain elements” and method CPSC-CH-C1001-09 for the determination of phthalates.

Migration of elements: EN 71-3:2013+A1:2014

This European Standard specifies requirements and test methods for the migration of aluminium (Al), antimony (Sb), arsenic (As), barium (Ba), boron (B), cadmium (Cd), chromium (III), chromium (VI), cobalt

(Co), copper (Cu), lead (Pb), manganese (Mn), mercury (Hg), nickel (Ni), selenium (Se), strontium (Sr), tin (Sn), organic tin and zinc (Zn) from toy materials and from parts of toys. The requirements are related to the migration from the following categories of toy materials:

- Category I: Dry, brittle, powder like or pliable materials;
- Category II: Liquid or sticky materials;
- Category III: Scraped-off materials.

Migration limits from toy materials are shown in table 9.

Element	Migration limit		
	Category I mg/kg	Category II mg/kg	Category III mg/kg
Aluminium	5 625	1 406	70 000
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
Barium	1 500	375	18 750
Boron	1 200	300	15 000
Cadmium	1,3	0,3	17
Chromium (III)	37,5	9,4	460
Chromium (VI)	0,02	0,005	0,2
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
Lead	13,5	3,4	160
Manganese	1 200	300	15 000
Mercury	7,5	1,9	94
Nickel	75	18,8	930
Selenium	37,5	9,4	460
Strontium	4 500	1 125	56 000
Tin	15 000	3 750	180 000
Organic tin	0,9	0,2	12
Zinc	3 750	938	46 000

Table 9: Migration limits from toy materials

The principle of the method is that soluble elements are extracted from toy materials using conditions that simulate the material remaining in contact with gastric juices for a period of time after swallowing. Then, the concentrations of soluble elements are determined quantitatively by different methods depending on the element.

For the purposes of this joint action, a method for determining general elements was applied. Chromium was analysed as total chromium (without further speciation), and tin was determined as total tin (no speciation for organic tin was applied). Therefore, the assessment related to Cr (VI) or organic tin could not be performed.

The standard specifies that a laboratory sample for testing shall consist of one toy in the form in which it is marketed. Test portions are taken from the toy materials of the single toy sample although identical materials in the toy may be combined and treated as a single test portion. The standard also specifies that test portions are taken from each colour of each toy material and in cases in which discrete specimens

cannot be separated physically, such test portions can be combined. In addition, if the total weight of available toy material is less than 10 mg, test portions are disregarded.

The materials of the toy are divided into categories (I, II or III), before starting the analysis. This is an important step as the material is prepared according to the category. Even more, within category III, and depending on the type of material (paper, coating, textile, polymers...) the sample treatment varies. The materials of the samples sent for testing have been divided according to table 10 below.

Category of material from the toy sample	Types of toys
Category I (dry, brittle, powder like or pliable)	Crayons, Plasticine, modelling clay
Category II (liquid or sticky)	Toys Paints / Finger Paints
Category III (coatings of paint, varnish, lacquer, printing ink, polymer, paper)	Activity Centres for very young children Bath toys Soft Books/Bath Books Dolls / Figures & Accessories Soft Toys Teething Rings Inflatable Toys Soft balls Rattles Puzzles Pull along / push along toys with / without cords Other Toys (painted) - wooden Other Toys (painted) - metal Mouth-Actuated Toys Other Toys

Table 10: Category of materials of toy samples sent for chemical testing at the laboratory

Figure 38 shows the distribution of materials in the samples received in the laboratory for the analysis of EN 71-3:2013.

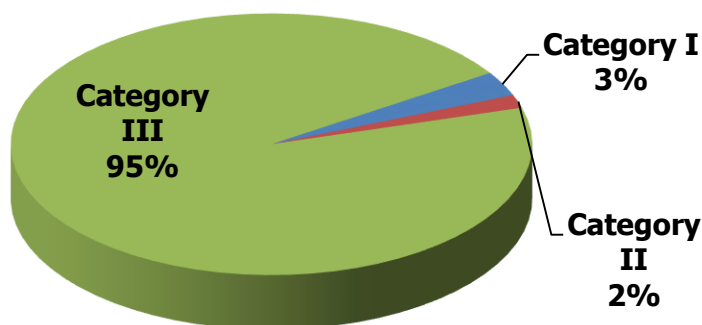


Figure 38: Distribution of categories of materials for the samples received for chemical analysis

Concerning the sampling procedure, in such cases in which the authority did not select the colours/materials to analyse, the laboratory decided on which colours/materials perform the migration of elements. As a general rule, this decision was made on the materials which are predominant in the toy sample or those parts that can be put more easily into the mouth.

After the selection of the materials, a portion for the analysis is taken. For coatings, the coating is removed by means of a scraper, in case of plastic materials; the portion is removed by cutting the material. In case of liquid paints, a portion of the sample is directly taken.

The portion for the analysis is weighed and registered. After that, diluted hydrochloric acid (HCL) is added and the pH of the solution is checked and adjusted. The concentration for coatings was 0.07 mol/l HCL and in the case of plastiline the concentration was 0.14mol/l HCL. The migration is performed under magnetic agitation at 37 °C. Once the corresponding agitation and stand times have finished, the solution is filtered and analysed by means of ICP-MS (Inductively Coupled Plasma with mass spectrometry detection).

Analysis under EN 71-3:2013 was also treated under EN 71-3:2013+A1:2014. This amendment introduces minor modifications for the sample preparation and mainly related to the pH control of the solutions during the migration stage.

The final individual test reports included the results obtained from testing the samples. As usual in chemical analysis, the test report also included specific descriptions of the materials analysed in the toy. Tables containing analytical results include individual result per material and element. A toy complied with EN 71-3:2013+A1:2014 when all accessible materials met the requirements related to migration limits for all accessible materials.

As agreed with the laboratory, only three different materials had to be chosen from each sample toy on which migration of elements was requested. However, some toys only had one or two different materials to analyse. On the other hand, other authorities selected up to 6 different materials.

The overall number of materials analysed under EN 71-3:2013+A1:2014 per country is shown in figure 39.

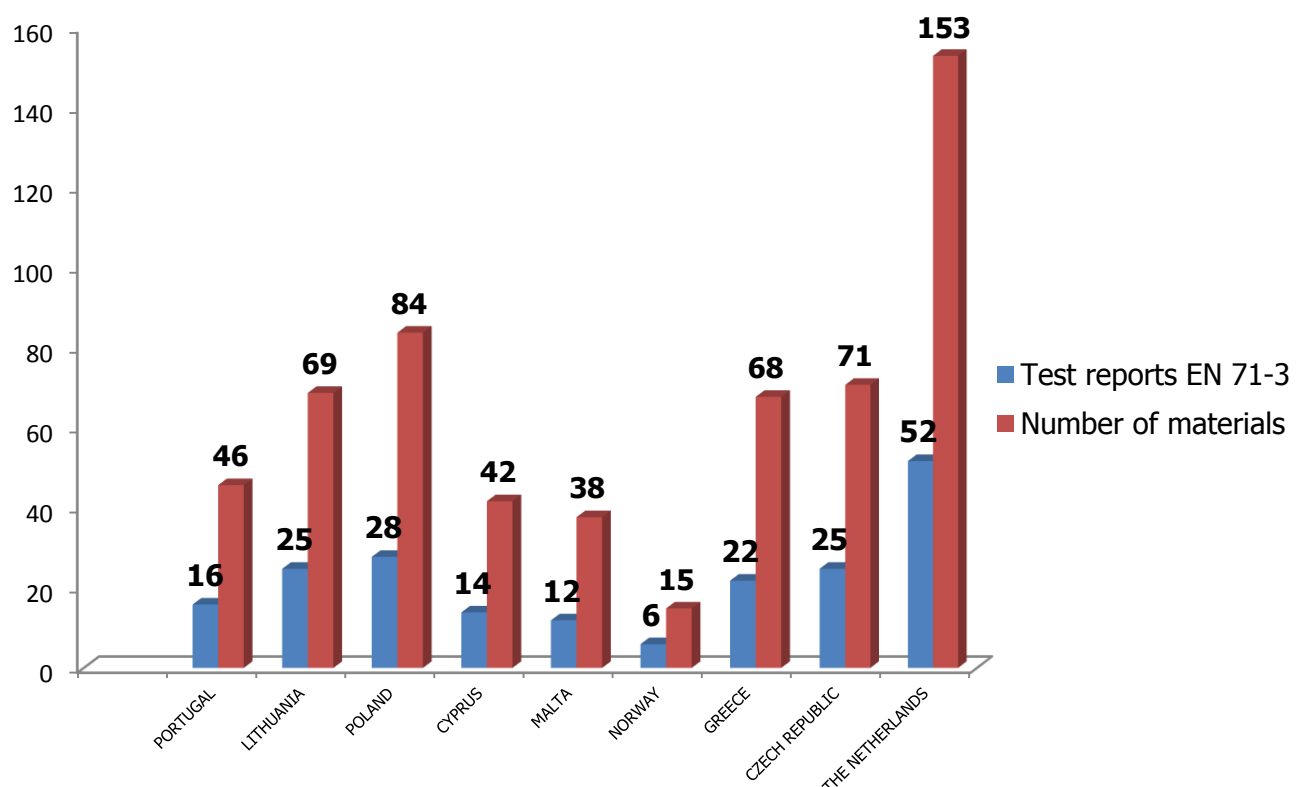


Figure 39: Distribution of materials analysed by country

Total number of toys analysed for the migration of elements is 200, however, the overall number of materials were 586.

Phthalates content

Some phthalates are regulated under REACH, Regulation (EC) No 1907/2006, Annex XVII, points 51 and 52. Phthalates classified as CMR (Carcinogenic, Mutagenic or toxic for Reproduction), as specified in CLP (Regulation (EC) No 1272/2008), are restricted by EU Toy Safety Directive 2009/48/EC.

REACH, Annex XVII, Point 51: Bis (2-ethylhexyl) phthalate (DEHP), Dibutyl phthalate (DBP) and Benzyl butyl phthalate (BBP) shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles.

REACH, Annex XVII, Point 52: Di-“isononyl” phthalate (DINP), Di-“isodecyl” phthalate (DIDP) and Di-n-octyl phthalate (DNOP) shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles which can be placed in the mouth by children.

Restriction applies to the combination of each group. A toy is not in compliance with REACH if the concentration of DEHP + DBP + BBP is greater than 0.1 %, or DINP + DIDP + DNOP is greater than 0.1%.

Related to the meaning of “which can be placed in the mouth”, the European Commission published a guidance document [\[2\]](#) which is used for the evaluation of the compliance of the toy.

Several phthalates are known as SVHC substances (Substances of Very High Concerns), under the terminology of REACH, due to their classification as toxic for reproduction (CMR substances). Furthermore DEHP, BBP and DBP and DIBP (Diisobutyl phthalate), are already included in annex XIV of the REACH Regulation. Those substances needs authorisation for their use (from 28 February 2015).

At this moment, REACH regulation does not address any particular method for the analysis of phthalates. There are some standards for the measurement of such substances ISO, EN, CPSC methods. It was agreed that the laboratory could use CPSC-CH-C1001-09 “Determination of phthalates” as a routine analysis for phthalates. The general approach of the method is to extract the material by means of a microwave extraction and then analyse the solution by GC-MS (gas-chromatography with mass spectrometry detection).

It is possible to perform the test by composite testing of a maximum of three similar materials. This procedure has an inconvenience: when the amount obtained does not allow the assessment of the compliance, an individual analysis of separate materials should be done as the limitation in REACH is related to materials.

This test does not need conditioning of the samples prior of the analysis; therefore, the materials selected are directly cut from the sample and weighed in a combined form directly in a microwave extraction vessel. A few millilitres of solvent are added to the vessel, which is closed and put into the microwaves. After the programme for the extraction, the solution is filtered and analysed by GC-MS.

Prior to the determination by GC-MS, the performance of the equipment is checked and calibrated. The calibration curve is also checked in terms of reproducibility, linearity and trueness. Additionally, each batch of samples are also analysed with an in-house reference material for the measurement of recovery.

The materials selected for the determination of phthalates are those that are susceptible to contain such substances. Soft materials plasticised films in bath books, head of a doll or inflatable toys can contain

plasticisers as additives, and therefore, phthalates may be present. Most of toy samples sent to the laboratory have been fully analysed according to phthalates content, as three materials have been analysed in each toy sample.

Figure 40 shows total analysis performed by country related to phthalates.

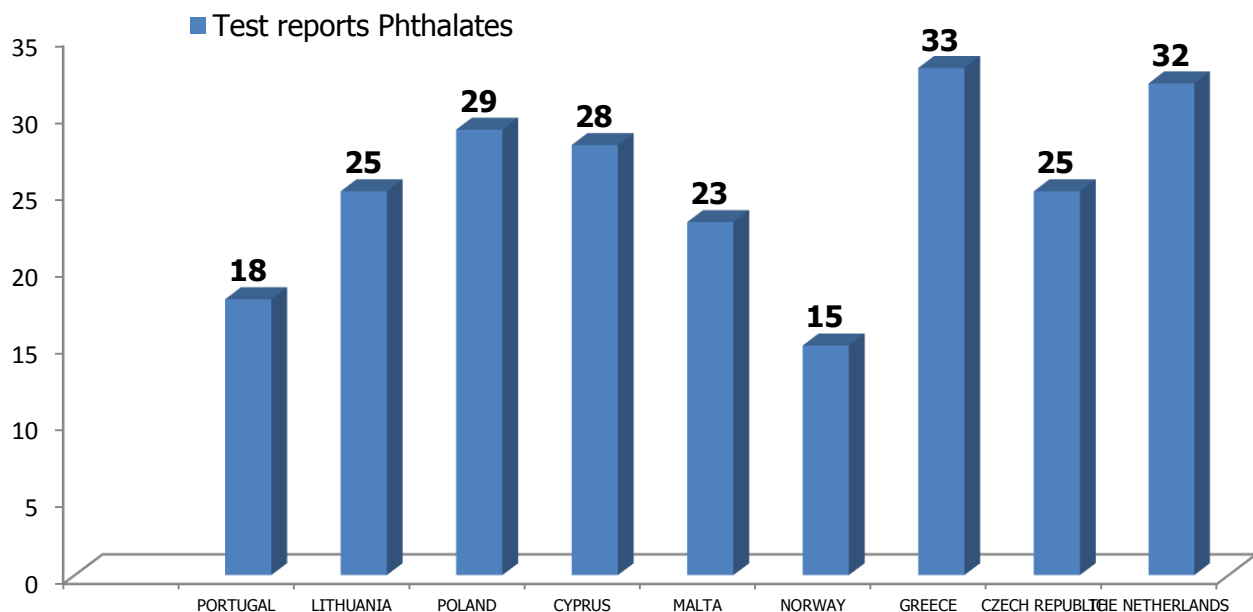


Figure 40: Phthalates analysis performed on the JA13 samples

As the phthalates analysis is made by means of GC-MS, some other phthalate substances not included in points 51 and 52 of the Regulation can be also measured in the same run. For the purposes of this joint action, Diisobutyl phthalate (DIBP) was also quantified in the samples. Additionally, the following phthalates were qualitatively analysed:

- Bis (2-methoxyethyl) phthalate (DMEP)
- 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)
- 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)
- Dipentyl phthalate (DPP)
- N-pentyl-isopentylphthalate
- Diisopentylphthalate
- 1,2-benzenedicarboxylic acid, dipentylester, branched and linear
- Dihexyl phthalate
- 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear, Di-NHexyl phthalate,

All of these phthalates are SVHC substances with the CLP classification CMR Repr. 1B (toxic for reproduction category 1B), except 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear, Di-NHexyl phthalate which is, in the moment of the writing of this report, proposed as CMR Repr. 2.

A toy is not in compliance with the EU Toy Safety Directive if the concentration of a substance classified as Repr. 1B is $\geq 0,3\%$ in accessible parts of the toy. DIBP (Diisobutyl phthalate) are classified Repr.1B, but due to a specific concentration limit, as specified in CLP, the substance is banned in toys in concentrations $\geq 5\%$. A new classification of this substance, with no specific concentration limit, is proposed.

3.2.3 Results of the tests

This section of the report includes in detail the test results along with some statistics according to different factors.

Test Results according to EN 71-3:2013+A1:2014

Taking into account the results of the **chemical tests** performed, Table 11 presents the non-compliances found according to this standard.

Category	Non-conformity detected	Limit
Crayons, Plasticine, modelling clay (CPM)	8 ± 2 mg/kg As 17 ± 5 mg/kg As	Category I of material for EN 71-3 Limit As: 3.8 mg/kg
Crayons, Plasticine, modelling clay (CPM)	51 ± 5 mg/kg Co	Category I of material for EN 71-3 Limit Co: 10.5 mg/kg
Other Toys (painted) - wooden (OTW)	340 ± 40 mg/kg Pb	Category III of material for EN 71-3 Limit Pb: 160 mg/kg

Table 11: Non-compliances found according to EN 71-3:2013+A1:2014

RESULTS: 3 of 200 samples tested were not conforming to the requirements mentioned of EN 71-3:2013. Different elements have been detected above the corresponding limits (see Table 11). Lead above the limit was found in one of the samples.

Concerning arsenic, found in one of the samples, it is important to highlight that the uncertainty of this measure in this level (category I of materials) is very high (around 30 %).

Besides, most of the samples of coatings gave quantifiable values of migration for the following elements: Al, Ba, B, Mn, Ni, Sr, Zn.

Measurable quantities of Co and Cu were found in some of the samples of coatings.

In two of the coatings on wood, quantifiable amounts of Pb were found. However, the amounts found were very different.

Some of the samples with coatings on metal gave migration values of Sn and Zn. In some cases, migration of Zn can be high (but under the limits indicated in the Directive on the Safety of Toys for category III).

Test Results according to Phthalate Content

In the case of phthalates, some non-compliances related to amounts higher than the limits permitted, were found in around 12 % of the samples tested. The phthalates mainly found were: DEHP, DINP, DIDP and DIBP. In many cases, the presence of phthalates is not due to a single substance, but the mixture of two of them.

None of the samples analysed for phthalates presented the following phthalates:

Bis (2-methoxyethyl) phthalate (DMEP)

1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)

1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)

Dipentyl phthalate (DPP)

N-pentyl-isopentylphthalate

Diisopentylphthalate

1,2-benzenedicarboxylic acid, dipentylester, branched and linear

Dihexyl phthalate

1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear, Di-NHexyl phthalate,

The phthalates present in these non-complying samples were DEHP, DINP and DIDP. Four of the samples presented a DBP content of about 0.03%. Additionally, some of the samples tested presented variable amounts of DIBP.

RESULTS: 27 of 228 samples tested did not meet the requirements mentioned in point 51 and/or 52 of REACH regulation annex XVII related to phthalates content. The main phthalates found in the non-complying samples were DEHP, DINP and DIDP in variable amounts.

RESULTS: 9 of 228 samples tested showed DIBP in amount above 0.1 % by weight of analysed material.

➤ Non-compliances related to point 51 Annex XVII REACH. DEHP

Concerning the presence of DEHP in amount over 0.1 % of plasticised material, table 12 shows the overall results found on the analysed samples. The maximum amount of DEHP found was 26 % by weight. BBP was present in none of the analysed samples and the amount of DBP quantified was below the limit in all samples.

Category	Result
Inflatable Toys	2,8 ± 0,2 % DEHP
Bath toys	17 ± 1 % DEHP
Bath toys	0.115±0.008 % DEHP
Bath toys	0,126 ± 0,008 % DEHP
Bath toys	24 ± 2 % DEHP
Bath toys	26 ± 2 % DEHP
Bath toys	15 ± 1 % DEHP
Soft Toys	0,17 ± 0,01 % DEHP
Bath toys	0,22 ± 0,02 % DEHP
Bath toys	12,1 ± 0,8 % DEHP
Rattles	21 ± 1 % DEHP
Soft Toys	25 ± 2 % DEHP
Dolls / Figures & Accessories	2,8 ± 0,2 % DEHP
Bath toys	14 ± 0,9 % DEHP

Table 12: Non-compliances found according to point 51 of REACH, Annex XVII

The ranges of DEHP content are shown by type of toy in table 13 and Figure 41 shows the number of samples according to DEHP levels found within the respective samples.

Category	% DEHP Content	Median of % DEHP
Inflatable Toys	2,8	2,8
Bath toys	0,1-26	12,06
Rattles	21	21
Soft toys	0,17-25	12,56
Dolls / Figures & Accessories	2,8	2,8

Table 13: Variation of DEHP content by type of toy

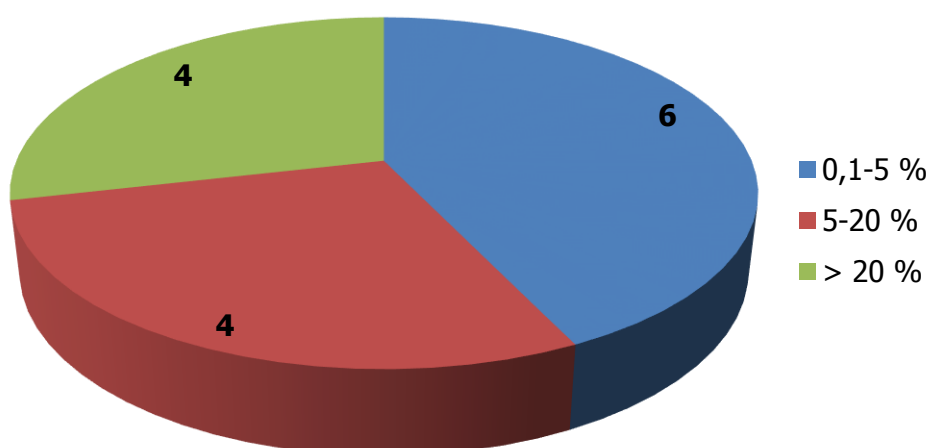


Figure 41: Number of samples according to level of DEHP

➤ **Non-compliances related to Point 52 Annex XVII REACH. DINP and DIDP**

Concerning the presence of DINP and DIDP in amount over 0.1 % of plasticised material, table 14 shows the overall results found on the analysed samples. The maximum amount of DINP found was 48 % by weight. Concerning DIDP, the maximum amount found in the analysed samples was 10 %.

DNOP was present in none of the analysed samples.

Category	Result
Bath toy	0,10 ± 0,02 % DINP ***
Bath toy	35 ± 3 % DINP 6,9 ± 0,7 % DIDP
Bath toy	40 ± 4 % DINP 6,8 ± 0,7 % DIDP
Bath toy	47 ± 4 % DINP 6 ± 1 % DIDP
Bath toy	48 ± 4 % DINP; 7 ± 1 % DIDP
Bath toy	0,18 ± 0,02 % DINP
Bath toy	45 ± 4 % DINP 9 ± 1 % DIDP
Bath toy	4,4 ± 0,4 % DINP
Bath toy	16 ± 1 % DINP 0,21 ± 0,02 % DIDP
Bath toy	7,8 ± 0,7 % DINP 0,07 ± 0,001 % DIDP
Doll / Figure & Accessories	0,16 ± 0,03 % DINP
Soft Toy	21 ± 2 % DINP 10 ± 1 % DIDP
Soft Toy	29 ± 3 % DINP 7,1 ± 0,7 % DIDP
Soft Toy	28 ± 3 % DINP 6,9 ± 0,7 % DIDP;
Soft Toy	30 ± 3 % DINP 6,9 ± 0,7 % DIDP
Soft Toy	19 ± 2 % DINP 1,7 ± 0,2 % DIDP
Rattle	1,9 ± 0,2 % DINP

Table 14: TNon-compliances found according to point 52 of REACH, Annex XVII

*** The first sample above was not considered by the authority as non-compliant due to the limit shown.

The ranges of DINP and DIDP content are shown by type of toy in table 15 & table 16 respectively.

Category	% DINP	Median of % DINP
Bath toy	0,1 - 48	24,35
Soft toy	19 - 30	21,48
Doll / Figure & Accessories	0,16	0,16
Rattle	1,9	1,9

Table 15: Variation of DINP content by type of toy

Category	% DIDP	Median of % DIDP
Bath toy	0,2 - 9	5,14
Soft toy	1,7 - 10	6,52

Table 16: Variation of DIDP content by type of toy

Graphically, the variation of the amount of DINP and DIDP is shown in figure 42. Figures 43 and 44 show the ranges of concentration of such phthalates found in the samples.

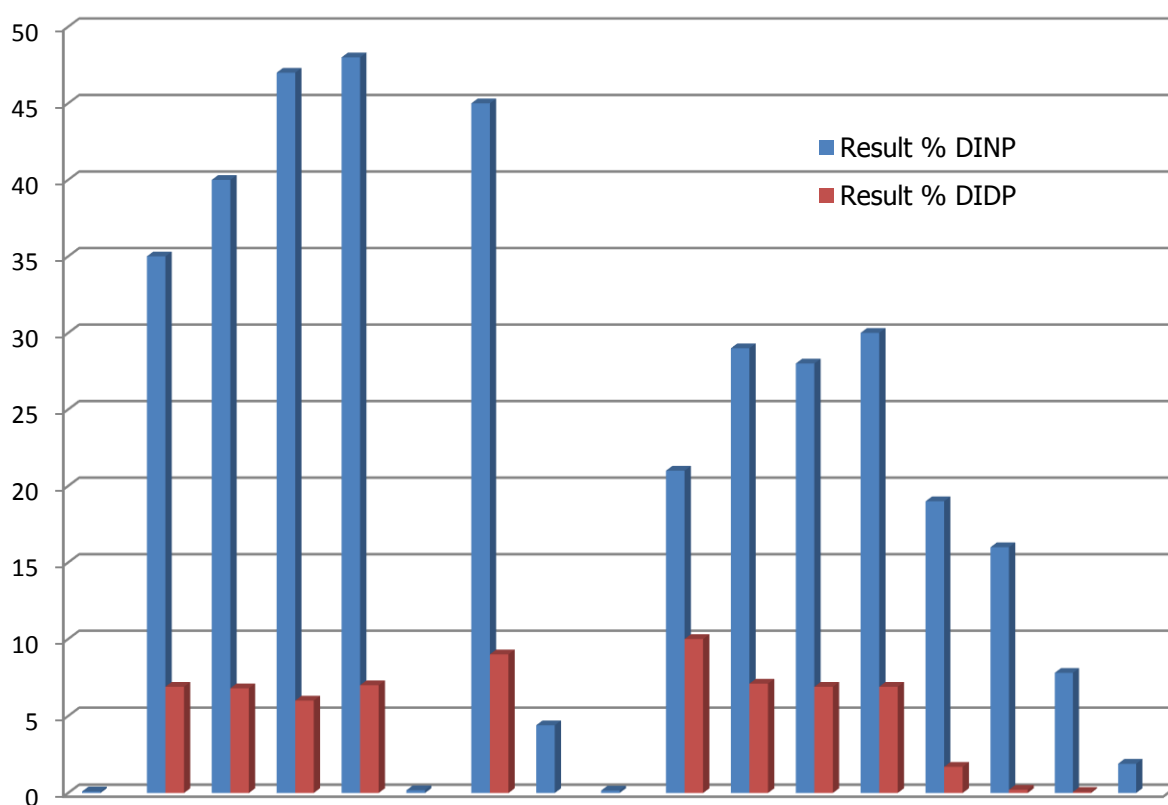


Figure 42: Amount of DINP and DIDP found in the samples

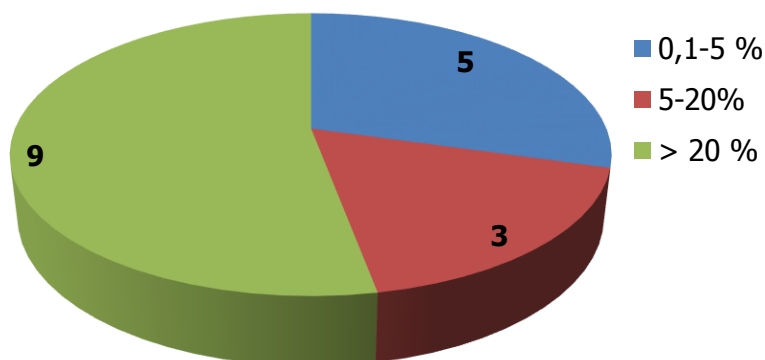


Figure 43: Number of samples according to level of DINP

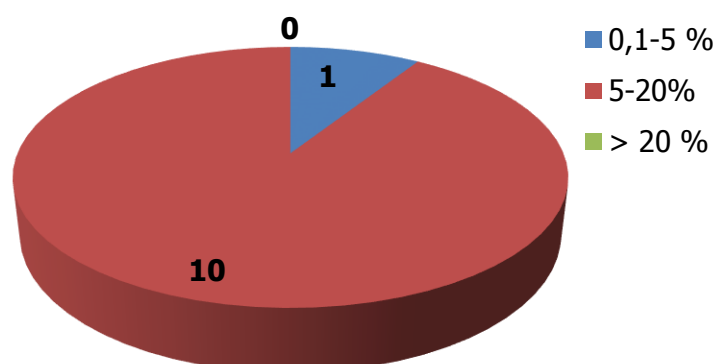


Figure 44: Number of samples according to level of DIBP

➤ **Annex XIV REACH. DIBP**

Finally, and concerning the presence of DIBP in amount over 0.1 % of plasticised material, table 17 shows the overall results found on the analysed samples. The ranges of % DIBP found within the samples are shown by type of toy in table 18, which also shows the median of % DIBP. The maximum amount of DIBP found was 21 % by weight.

Sample	Category	% DIBP
PT-IT-01-01*	Inflatable Toys	0,23 ± 0,02 %
LT-BT-02-02	Bath toys	6,43 ± 0,01 %
LT-BT-09-01	Bath toys	2,87 ± 0,01 %
LT-BT-11-01	Bath toys	Nº 2: 15.81±0.03%; N° 3: 0.17±0.02%; N° 4: 0.23±0.02%
LT-BT-14-01	Bath toys	0,94 ± 0,01 %
PL-BT-14-01	Bath toys	Nº2 10,85 ± 0,02 % DIBP, N°3 9,40 ± 0,02 % DIBP, ; N°4 11,15 ±0,02 % DIBP,
PL-BT-15-01	Bath toys	0,23 ± 0,02 %
GR-IT-01-01	Bath toys	20,70 ± 0,04 %
CZ-SB-01-02	Soft Toys	14,67 ± 0,03 %

Table 17: Samples with more than 0.1 % by weight of DIBP (by analysed material)

Category	% DIBP	Median of % DIBP
Inflatable toys	0,23	0,23
Bath toys	0,2-21	7,16
Soft toys	14.67	14.67

Table 18: Variation of DiBP content by type of toy

Figures 45 and 46 show the amounts and the variation in the range of concentration for DIBP found in the analysed samples that have more than 0.1 % by weight.

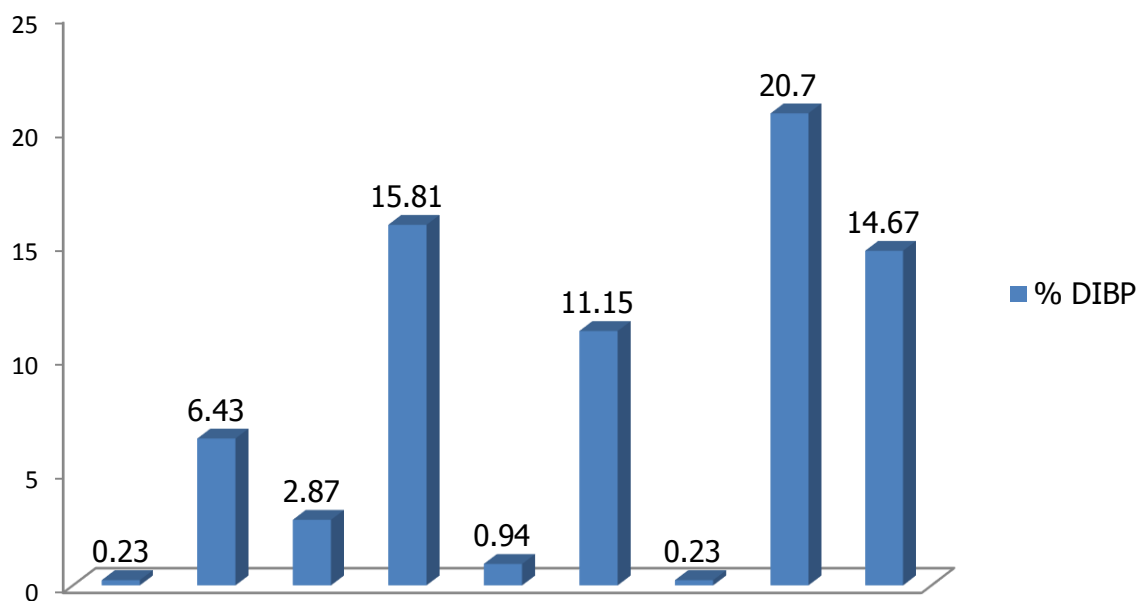


Figure 45: % DIBP found in the samples (> 0.1 %)

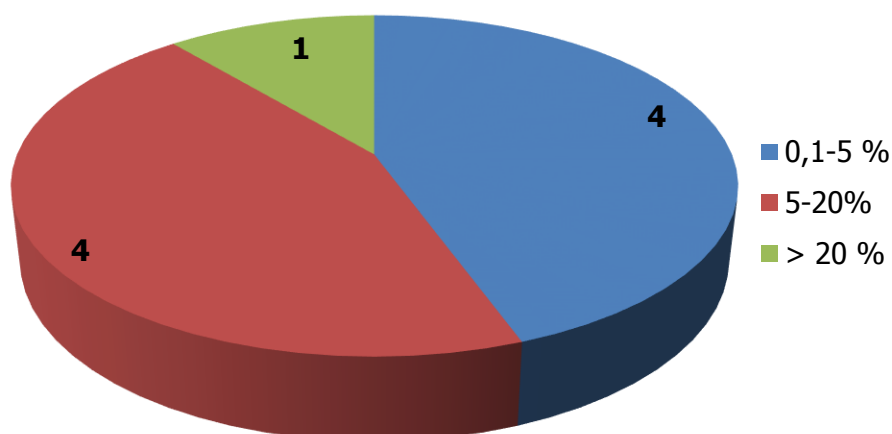


Figure 46: Number of samples according to level of DIBP

One needs to remember that toys with more than 5% DIBP are not compliant with the Toy Safety Directive 2009/48/EC. Four of these nine samples also had concentrations of DEHP higher than the limit of 0.1%. Four other samples only had DIBP concentrations but were well above the 5% limit. There was only one sample which had a concentration of DIBP less than 5% (and the amount was 0,23%). Additionally, this sample did not have any other phthalate with a higher level than the limit.

3.3 Warnings, Markings & Instructions for Use

It was agreed that for this particular joint activity, the participating authorities were directly responsible for checking warnings, markings and instructions for use as per Clause 7 of the EN71-1:2011+A3:2014.

Table 19 shows a summary of the particular aspects checked by the inspectors. The table shows the number and percentage non-compliance found out of the total number of samples extracted from the market. No distinction is being shown here between samples tested for mechanical / physical requirements and samples tested for chemical requirements. The reason for this is that all samples need to have such information available.

The percentage overall non-compliance related to the six areas checked below has been found to be 40%. There were some (7%) which did not even have a CE mark. 23% did not have the language as determined by the respective national authority. This is of particular importance to consumers who need to fully understand the information available on the toy. Additional information is found within Table XX itself. Again, this did not mean that 40% of the samples were unsafe. Risk assessment had to be performed on each sample, taking into consideration both the technical results, the information below and also all other aspects, before a final outcome was decided upon by each market surveillance authority.

Information checked by Market Surveillance Inspectors	Number of non-compliant Samples	Percentage out of 604 samples
Are labels and warnings visible, legible, permanent and in a language or languages as determined by the national authority? YES / NO	141	23%
Manufacturers and importers must ensure that the toy is accompanied by instructions and safety information in a language or languages as determined by the national authority. Are they present? YES / NO	141	23%
Does it have a CE mark? YES/NO	42	7%
Does the toy (or where it is not possible on the packaging or in the document accompanying the toy) include the manufacturer's name, (or authorised representative or importer), registered trade name or registered trade mark AND the address at which to be contacted? YES/NO	71	12%
Manufacturers must ensure that their toys bear a type, batch, serial or model number or other element allowing their identification, or where the size or nature of the toy does not allow it, that the required information is provided on the packing or in a document accompanying the toy. Is this present? YES/NO	84	14%
Is the specific type of toy in line with the respective clauses (from 7.3 up to 7.22) of EN71-1 standard?	108	18%
OVERALL COMPLIANCE YES / NO	243	40%

Table 19 - Percentage non-compliance mainly on Warnings, Markings and Instructions for use

3.4 Final Comment

One needs to stress that section 3 had dealt with testing procedures and non-compliances found within the respective toy samples sent for testing. Section 3.3 also shows the level of non-compliance found within warnings, markings and instructions for use. Although market surveillance authorities are able to take action on any non-compliance found, they usually utilise this technical information to ultimately take a more informative decision on the risk associated with the product.

Risk assessment is by far the most important next step in such a process whereby all the market surveillance authorities had to risk assess the samples. Section 4 tries to delve into the area of risk assessment as well as measures taken by the market surveillance authorities.

4 Risk Assessment & Measures taken

After all the laboratory test results were finalised, a special meeting was held at the laboratory premises itself to see and discuss the non-compliances found within the samples tested. More importantly, this meeting was used to try to come up with internal guidance on how to perform risk assessment. This ensured more consistency and coordination in the final results achieved, including those related to measures taken by the respective market surveillance authorities.

Figure 47 below, extracted from the European Commission guidelines on risk assessment [3], show the two main factors leading to risk level: (i) the severity level of the injury and (ii) the probability of damage occurring during the foreseeable lifetime of the product. During the meeting held at the laboratory, AIJU, in Spain, most of the samples were discussed individually with all the group as well as the AIJU experts. Risk assessment templates were developed for internal use by this working group to help ensure a more synergised approach to this important area. This helped to come up with a common approach in relation to the severity and probability factors for varying scenarios, which in turn ensured a more synergised approach to risk assessment and ultimately the measures taken too.


Risk level from the combination of the severity of injury and probability					
Probability of damage during the foreseeable lifetime of the product		Severity of injury			
		1	2	3	4
<div>High</div>  <div>Low</div>	> 50 %	H	S	S	S
	> 1/10	M	S	S	S
	> 1/100	M	S	S	S
	> 1/1 000	L	H	S	S
	> 1/10 000	L	M	H	S
	> 1/100 000	L	L	M	H
	> 1/1 000 000	L	L	L	M
	< 1/1 000 000	L	L	L	L
S — Serious Risk					
H — High risk					
M — Medium risk					
L — Low risk					

Figure 47 - Combination of Injury and Probability extracted from the respective Commission Guideline

It is important to remember that the whole exercise was not a random sampling exercise but rather a focused approach by market surveillance inspectors to identify those samples which showed the strongest signs of possible non-compliances. Whereas this can be done quite effectively with regards to determination of physical / mechanical faults within a particular sample (since inspectors can actually see signs of non-compliances with training and experience), it was far more difficult for inspectors to determine whether samples had any chemical non-compliances in them. In this case, the inspectors were asked to focus upon particular type of product groups which could possibly yield higher incidences of non-compliances related to migration of certain elements and phthalate content.

Therefore, the results DO NOT REPRESENT IN ANY WAY THE OVERALL CURRENT SITUATION IN THE SINGLE MARKET. For this to be determined a professional statistical exercise would need to be performed which goes beyond the scope of this market surveillance activity.

4.1 Physical & Mechanical Requirements

4.1.1 Risk Assessment

Table 20 and Figure 48 show the results of risk assessment in relation to toys tested for physical and mechanical requirements. 35% of all the toys showed a “Serious Risk” level. The absolute majority of these samples had non-compliances in the area of small parts (Clause 5 of EN71-1). Another 2% had a “high risk” level whereas another 3% had a “medium risk” level. This shows that 40% of all toys had some form of risk associated with them.

On the other hand, it is important to note that, even though this was not a random exercise, 60% of all toys sent for testing were classified by the respective market surveillance authorities as not having any significant form of risk.

It is also worth noting that the percentages and amounts related to non-compliances do not necessarily match the percentages related to risk levels. This is because the risk level of each sample is ultimately determined by the market surveillance authority after a proper risk assessment is carried out.

Risk Level	Number of Samples	Percentage out of 265 total samples
Serious Risk	93	35%
High Risk	6	2%
Medium Risk	7	3%
Low Risk	0	-
No Particular Significant Risk Factor Identified	159	60%

Table 20 - Risk Level for various samples tested against mechanical / physical requirements

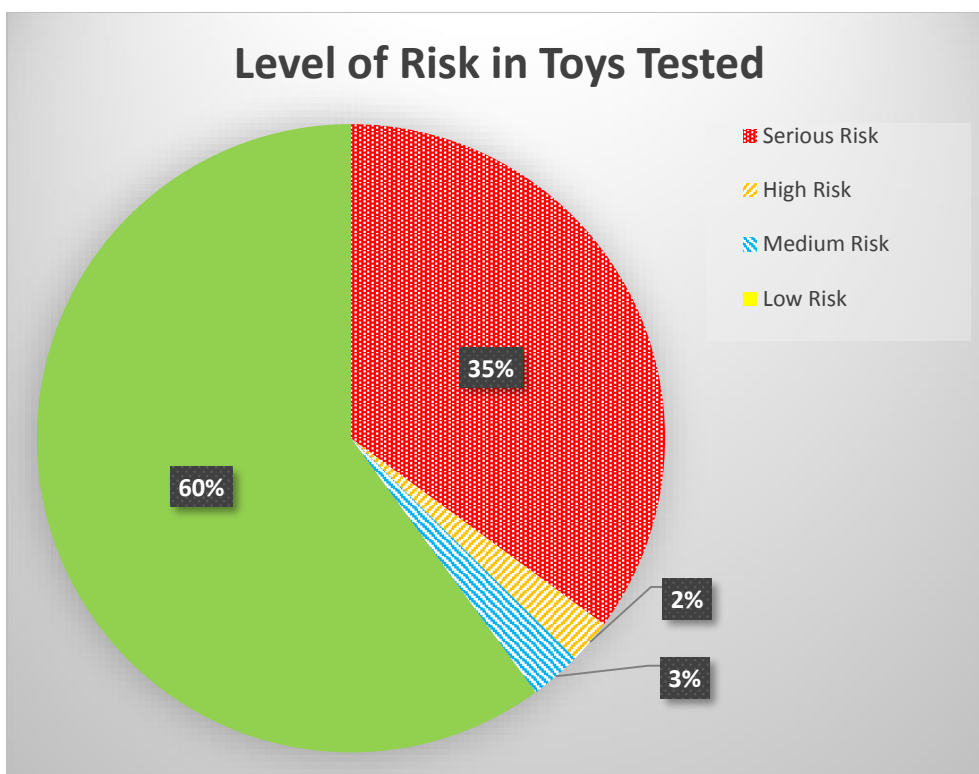


Figure 48 - Pie-chart showing distribution of risk levels in toys tested for Physical / mechanical requirements

Risk Factor by Categories

Table 21 below shows the respective risks found within each particular toy product group focused upon by this joint market surveillance exercise.

Although some of the toy product groups may have too few samples to really determine whether it is an indication related to that group, those with higher number of samples may be more indicative. However, again, this does NOT show any relevance to the actual safety level of the market itself but it could be of particular interest to a market surveillance authority since it could help to zoom in on those areas which could possibly yield higher levels of non-compliances.

PRODUCT DESCRIPTION	CODE	TOTAL NUMBER OF SAMPLES TESTED	Total Non-compliant Samples	Medium Risk	High Risk	Serious Risk	TOTAL Samples with Risk Factor	% of total samples tested from each product group
Rattles	R	53	21	2		15	17	32.1%
Pull along / push along toys with / without cords	PA	38	23			15	15	39.5%
Soft Toys	ST	27	14		2	11	13	48.1%
Bath toys	BT	23	7			7	7	30.4%
Puzzles	P	12	3		1	1	2	16.7%
Teething Rings	TR	11				0		0.0%
Dolls / Figures & Accessories	DFA	8	2	1		2	3	37.5%
Soft balls	SB	5	1			1	1	20.0%
Activity Centres for very young children	AC	4	3			3	3	75.0%
Soft Books/Bath Books	B	3	1		1	0	1	33.3%
Mouth Actuated Toys	MA	3	1			1	1	33.3%
Crayons, Plasticine, modelling clay	CPM	1				0		0.0%
Inflatable Toys	IT	1	1			1	1	100.0%
Other Toys (painted) - metal	OTM	4	2		1	1	2	50.0%
Other Toys (painted) - wooden	OTW	23	12	1		12	13	56.5%
Other Toys	O	49	32	3	1	23	27	55.1%
TOTAL		265	123	7	6	93	106	40.0%

Table 21 - Risk levels according to each Toy Product Group tested for mechanical / physical requirements - showing also number of non-compliant samples within each product type

It is worth noting that in the case of DFA and OTW product groups, the number of non-compliant samples is less than the number of samples having a risk level. This is mainly due to additional information available to the surveillance authority after the actual testing, upon which the risk was determined and action taken.

4.1.2 Measures taken

With regards to the actual measures taken, table 22 and Figure 49 show a generic breakdown of the most common type of measures taken by market surveillance authorities. 8 samples were recalled back from consumers whereas by far the most predominant action was “sales-bans / withdrawals” from the market. Some authorities are still performing some actions. This could be due to various reasons depending on the particular case in question.

Measures taken	Number of Samples	Percentage out of all Measures taken (including works-in-progress)
Recalls	8	6%
Sales-bans / Withdrawals	74	61%
Minor / corrective measures	6	5%
Works-in-progress	34	28%

Table 22 - Measures taken in relation to toys found not complying with mechanical & physical requirements

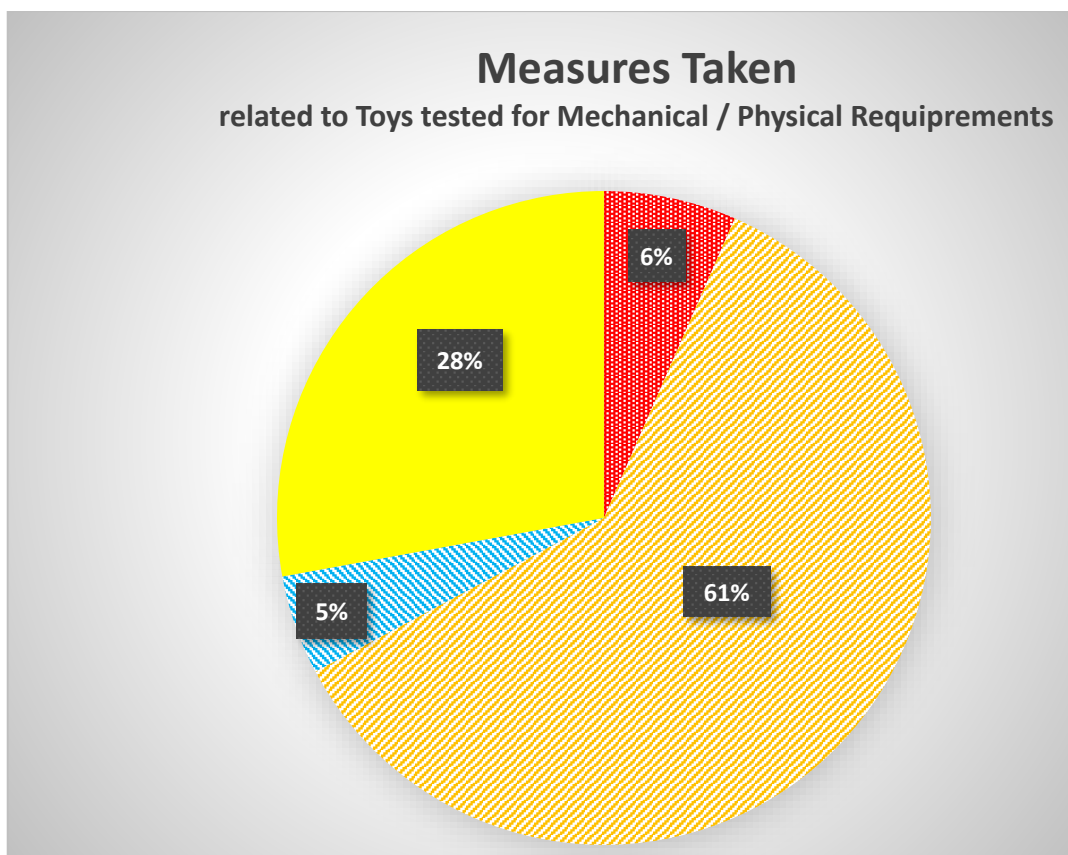


Figure 49 - Pie-chart showing breakdown of measures taken on toys that were found not to comply with mechanical & physical requirements

Voluntary	31	28.2%
Non-voluntary	79	71.8%

Table 23 - Voluntary versus non-voluntary actions taken by market surveillance authorities

Table 23 above shows that the majority of actions taken (around 72%) by market surveillance authorities were non-voluntary, that is, market surveillance authorities took direct action from their end. This could mainly be due to the fact that the majority of the cases had a “serious risk” level and therefore surveillance authorities preferred to take direct action from their end by enforcing the respective action upon the respective economic operators.

RAPEX ALERTS Initiated	80
Inputted in ICSMS	40

Table 24 - RAPEX Alerts & ICMS Notifications

As can be seen from Table 24 above, the market surveillance authorities already indicated that there will be at least 80 RAPEX Alerts, some of which are still underway. On the other hand, there were 40 ICSMS notifications. Given that the database -ICSMS - is an internal database for market surveillance authorities, it is surprising that only 40 notifications have been inserted. This may also be particularly due to the problem that at this point in time there does not seem to be clear guidance on what needs to be entered into ICSMS by the respective market surveillance authorities.

4.2 Chemical Requirements

The risk levels identified within the chemical requirements were found to be much lower than those related to mechanical & physical requirements. This could be associated to the fact that it was much more difficult for inspectors to identify any form of non-compliance before actually testing the sample. Additionally, it could also mean that manufacturers are more alert on the type of chemicals that should not be used in toys, with a result that the market seem to only have a few samples which show considerable risk. The truth is possibly a mix of these two possible answers.

4.2.1 Risk Assessment

Migration of certain elements as per EN 71-3:2013

As show in Table 25 and Figure 50, it is interesting to note that out of 200 samples tested for migration of certain elements in line with EN71-3:2013, only 3 were found to be non-compliant. Out of these 3 samples, only one was ultimately determined to have a “serious risk” level, with another sample having a “high risk” level. The last remaining sample is still pending and action will be taken once more information is available to the respective market surveillance authority.

Risk Level	Number of Samples	Percentage out of 200 total samples
Serious Risk	1	0.5%
High Risk	1	0.5%
Medium Risk	0	0.0%
Pending	1	0.5%
No Particular Significant Risk Factor Identified	197	98.5%

Table 25 - Risk levels associated with samples tested for EN71-3:2013

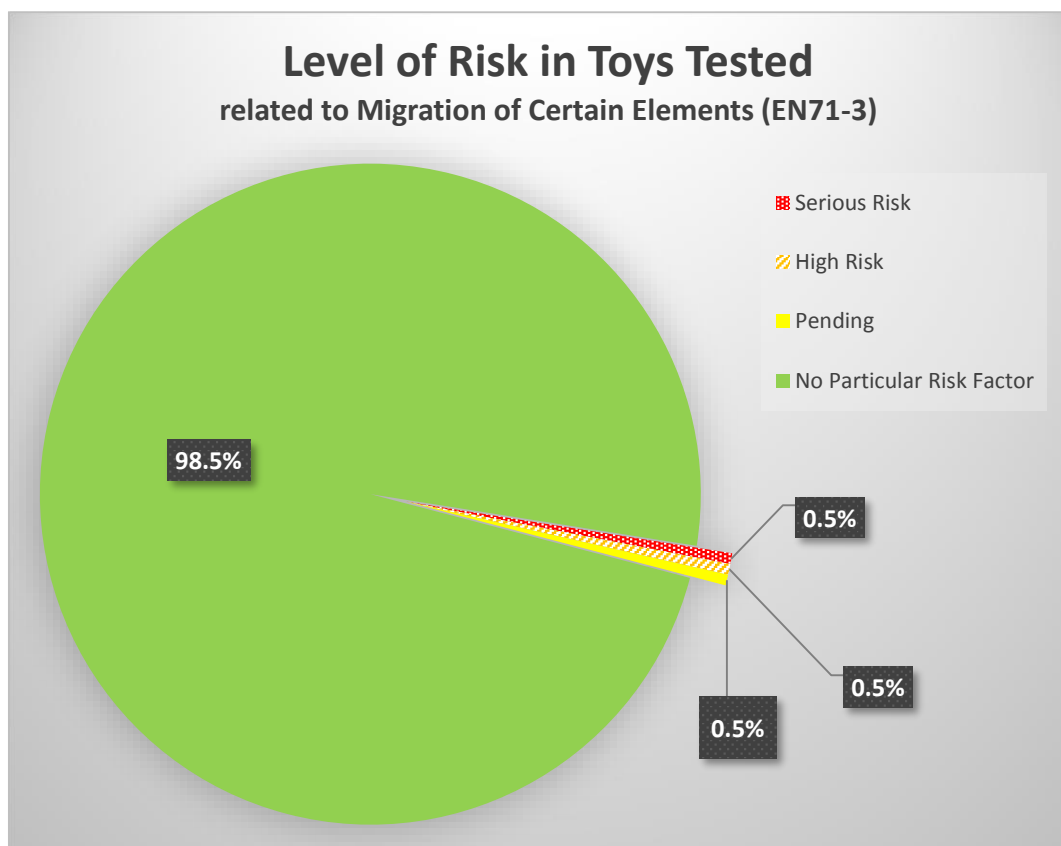


Figure 50 - Pie-chart showing distribution of risk levels in relation to toys tested for migration of certain elements in line with EN71-3:2013.

Table 26 below shows the breakdown of product types tested and the two particular samples which showed a high and serious level of risk.

PRODUCT DESCRIPTION	CODE	Total Samples tested according to EN71-3	Total Non-compliant Samples	High Risk	Serious Risk	TOTAL Samples with Risk Factor	Percentage out of total samples tested
Pull along / push along toys with / without cords	PA	23					
Crayons, Plasticine, modelling clay	CPM	13	2	1		1	7.7%
Puzzles	P	12					
Soft Toys	ST	7					
Toy Paints / Finger Paints	TFP	7					
Bath toys	BT	4					
Rattles	R	4					
Mouth Actuated Toys	MA	2					
Soft balls	SB	1					
Activity Centres for very young children	AC	1					
Other Toys (painted) - metal	OTM	10					
Other Toys (painted) - wooden	OTW	103	1		1	1	1.0%
Other Toys	O	13					
TOTAL		200	3	1	1	2	1.0%

Table 26 - Risk levels associated with respective Toy Product Types tested for EN71-3:2013 - showing also number of non-compliant samples within each product type

In the case of the sample identified as having a serious risk (from the toy category OTW), the sample resulted in a migration of lead of 340 ± 31 mg/kg Pb. With regards to the other case shown above as “high risk” within category “CPM”, cobalt migration of 51 ± 5 mg/kg Co was found in that particular sample. With regards to the remaining non-compliant sample, the respective market surveillance authority is currently liaising with the market surveillance authority from where the product originated in order to take action accordingly.

Phthalates

Risk Level	Number of Samples	Percentage out of 228 total samples
Serious Risk	28	12.3%
High Risk	0	0.0%
Medium Risk	1	0.45%
Low Risk	1	0.45%
No Particular Risk Factor Identified	198	86.8%

Table 27 - Risk level of samples tested for phthalate content

Table 27 and Figure 51 show the level of risks associated with the samples tested for phthalates. Again, most of the samples (around 87%) did not have any particular significant risk although it was found to be not as high as in the case of samples tested for migration of elements in line with EN71-1:2013.

It may be worth noting that these include 3 samples which had significant non-compliance to DIBP, well over the limit of 5% (which is the limit stipulated within the Toy Safety Directive 2009/48/EC). More information about this type of phthalate can be found within section 3.2 of this document.

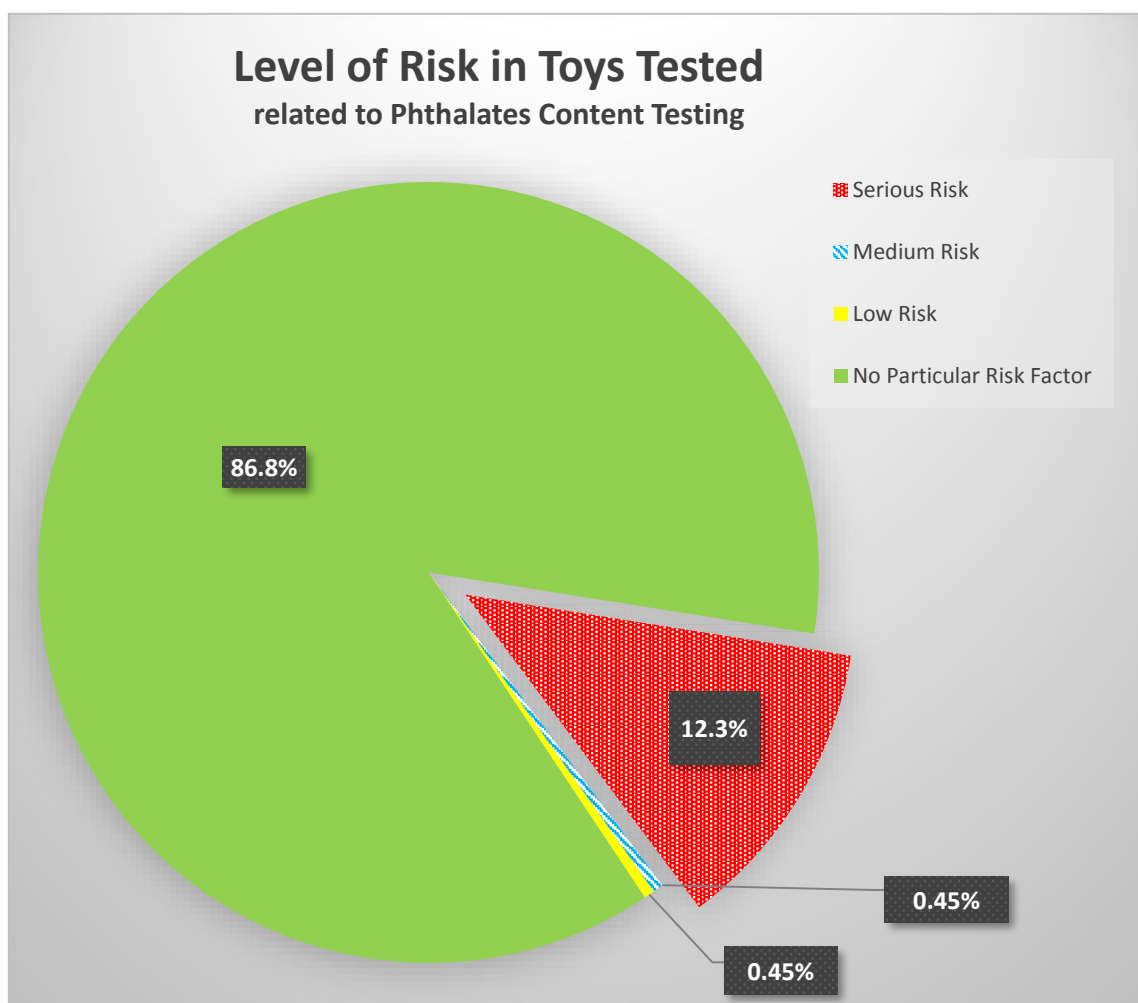


Figure 51 - Pie-chart showing risk levels associated with samples tested for phthalate content

28 samples (which constitute 12.3% of all samples tested for phthalate content) were classified by market surveillance authorities as having a “serious risk” and the respective breakdown of product types can be found within Table 28 below. Bath toys, dolls / figures, soft toys, rattles and inflatable toys were the only type of toys which had risk. In the case of all the other groups, the respective market surveillance authorities did not find any risk.

PRODUCT DESCRIPTION	CODE	TOTAL Samples tested for Phthalates	Total non-compliant Samples	Low Risk	Medium Risk	High Risk	Serious Risk	TOTAL Samples with Risk Factor	Percentage out of total samples tested in that category
Bath toys	BT	89	17	1	1		15	17	19.1%
Dolls / Figures & Accessories	DFA	29	2				2	2	6.9%
Teething Rings	TR	23							
Soft Toys	ST	20	6				8	8	40.0%
Soft Books/Bath Books	B	14							
Rattles	R	12	1				1	1	8.3%
Soft balls	SB	10							
Inflatable Toys	IT	6	1				2	2	33.3%
Mouth Actuated Toys	MA	2							
Pull along / push along toys with / without cords	PA	1							
Other Toys (painted) - wooden	OTW	1							
Other Toys	O	21							
TOTAL		228	27	1	1	0	28	30	13.2%

Table 28 - Risk levels associated with respective Toy Product Types tested for Phthalate Content - showing also number of non-compliant samples within each product type

In the case of Table 28 above, these include risk levels for 3 samples having considerably high DIBP levels between 10% to 20% weight by weight (w/w). Those particular three samples were classified by the market surveillance authorities as “serious risk” in view of this high level of DIBP and are included within the above table in the following product descriptions: 1 bath toy, 1 inflatable toy and 1 soft toy.

Additionally, the number of non-compliant samples are less than the number of samples showing a risk level. This again is mainly due to certain samples that were considered by the market surveillance authority as having a risk in view of the content of DIBP found within them. One needs to remember that toys with over 5% DIBP do not comply with the Toy Safety Directive. However, the CLP Regulation specifies even lower limits.

4.2.2 Measures taken

Migration of certain elements as per EN 71-3:2013

Only 3 samples out of 200 samples tested did not comply within the levels indicated within EN 71-3:2013. One of these samples has not yet been classified by the respective authority as to what level of risk it has since it is awaiting from another Member State some information on **when** it was placed on the market. This will make a difference as to whether this sample is actually compliant or not to the respective Toys Directive (either 2009/48/EC or 88/378/EEC).

The other two samples, as can be seen in Table 25 further above, have been classified as samples with high risk and serious risk respectively. In these particular two samples, one of them is still classified as works-in-progress since the responsible economic operator has been taking voluntary action and is being monitored by the market surveillance authority.

In the case of the other sample, a non-voluntary sales-ban / withdrawal has taken place directly by the respective market surveillance authority and a RAPEX alert has been issued accordingly.

Phthalates

In the case of phthalates, there were 2 recalls from consumers, 19 sales-bans / withdrawals and 4 minor / corrective measures. 5 samples were still considered as “works-in-progress” at the time that this document was finalised. This breakdown can be found in Table 29 and Figure 52 respectively.

Measures taken	Number of Samples	Percentage out of all Measures taken (including works-in-progress)
Recalls	2	6.5%
Sales-bans / Withdrawals	19	61.3%
Minor / corrective measures	4	12.9%
No action	1	3.2%
Works-in-progress	5	16.1%

Table 29 - Measures taken in connection with phthalate non-compliances

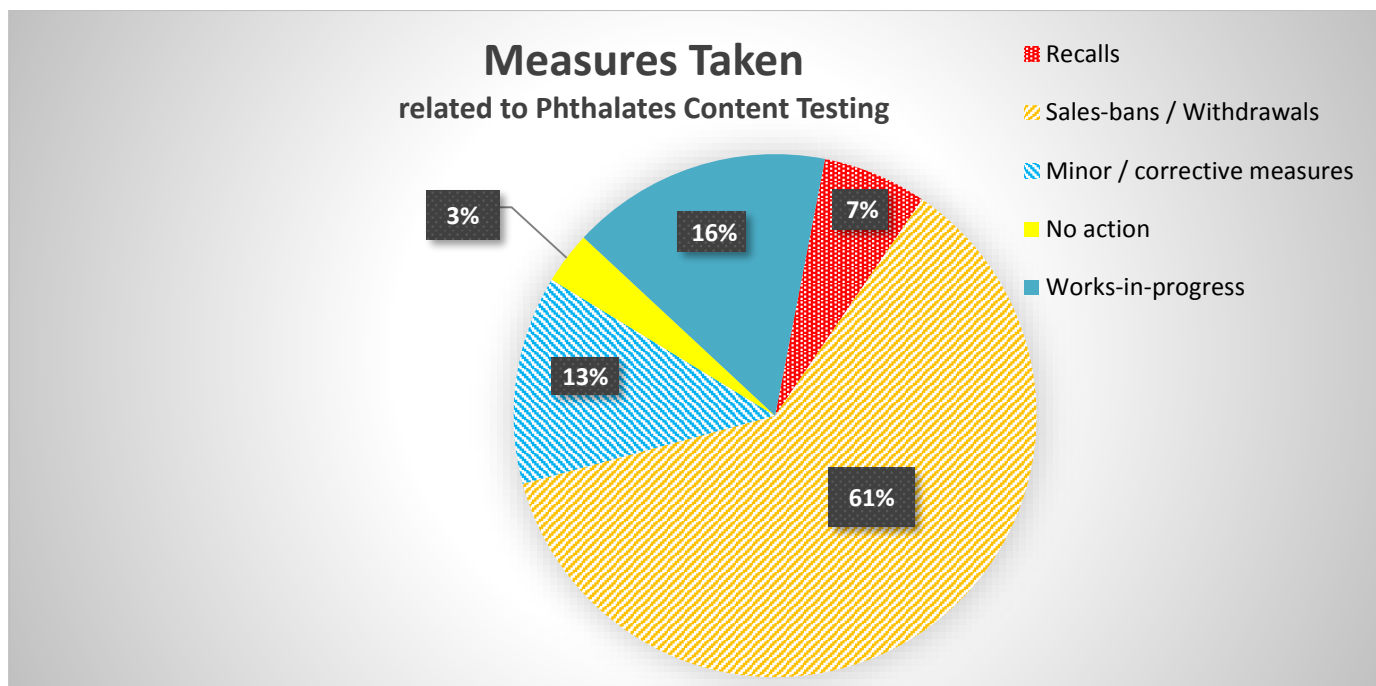


Figure 52 - Pie-chart depicting the type of measures taken in relation to samples with phthalate non-compliances

Again, most of the measures taken were not voluntary (64.3%), showing that the market surveillance authorities preferred to take direct enforceable action from their end. This could be related to the fact that most of the actions were taken on samples showing “serious risk”.

Voluntary	10	35.7%
Non-voluntary	18	64.3%

Table 30 - Percentage of Voluntary / non-voluntary measures

Table 31 show that 21 RAPEX alerts are in the process of the being issued. In the case of ICSMS, only 6 notifications were inserted in this database. Again, this could be due to the fact that there is no proper guidance as to what kind of notifications should be included within ICSMS.

RAPEX Alert initiated	21
Inputted in ICSMS	6

Table 31 - RAPEX & ICSMS Notifications

5 Liaisons

5.1 Involvement of stakeholders

The participating authorities within this joint surveillance activity wished to involve as many stakeholders as possible. Open sessions for external stakeholders were organised for each meeting, except the one organised at the laboratory itself. This was a closed session meeting in view that individual samples and sensitive information was discussed amongst market surveillance authorities.

The following stakeholders actively participated in these meetings:

☐ ANEC, the European Consumer Voice in Standardisation,

ANEC is the European consumer voice in standardisation. Their membership is open to representatives of national consumer organisations from 33 countries (EU, EFTA and accession countries).

☐ CEN - The European Committee for Standardisation

More than 50.000 technical experts from industry, associations, public administrations, academia and societal organizations are involved in the CEN network that reaches over 600 million people. 33 National Standards Bodies make up the CEN membership and they represent CEN in their country, besides various other affiliates.

☐ EUROCOMMERCE

EuroCommerce is the voice for around six million retail, wholesale, and other trading companies. Their members include national commerce federations in 31 countries, Europe's 27 leading retail and wholesale companies, and federations representing specific sectors of commerce.

☐ TIE - Toy Industries for Europe

TIE is the trade association for the European toy industry. TIE provides a unique source of information both for and on the toy industry in Europe. At present membership includes fourteen direct member companies and most national toy associations, representing approximately 80% of European toy sales.

☐ Toys Notified Body Group

The Member States, EFTA countries (EEA members) and other countries with which the EC has concluded Mutual Recognition Agreements (MRAs) and Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products (PECAs) have designated Notified Bodies, established per directive. The Notified bodies' assessment of products' conformity with the EU directives is extremely important not only for manufacturers but also for market-surveillance activities.

5.2 Customs

It was agreed by the participating authorities that this particular exercise was to be done directly by the market surveillance authorities themselves. However, the checklists used by the inspectors for this particular exercise may be possibly useful for Customs inspectors as well. A copy of this checklist will be eventually sent to DG-TAXUD for eventual distribution to Customs authorities, in order to see whether parts of this checklist may be adapted within any existing Customs checklists that they already have within the area of toys.

5.3 Other Liaisons

At Commission level, both DG-JUST and DG-GROW were involved from the beginning of this activity. This ensured that the Commission was being kept fully up-to-date with all the respective activities. Representatives from both DGs were invited for each meeting, ensuring that related information was cross-shared between market surveillance authorities and the Commission.

This activity was mainly done by the direct participation of 10 EEA Countries. However, it was decided from the beginning that this working group had to closely liaise with all the TOY-ADCO members so that the information is cross-shared with a much wider network of market surveillance authorities. For this reason, the Task Leader was invited to give updates and presentations during each TOY-ADCO meeting. Additionally, the priority list for future joint actions on toys, developed by this working group, involved all the TOY-ADCO members too. A document on these toy priority groups was developed by this working group and also circulated and discussed amongst stakeholders.

Besides all the above, the autumn and spring market surveillance workshops coordinated directly by PROSAFE were used as a basis for further discussion with all the participants of the whole joint action - JA2014. One needs to remember that although this activity involved the direct participation of 10 EEA Countries, the whole joint action involved 25 market surveillance authorities from 21 different countries within the European Economic Area. This ensured that the good practices and experiences, including challenges related to this activity, were all discussed and shared with a much wide group across Europe.

Liaison was also established from the start with the e-Learning working group (JA2013) in order to give further input and assistance to that e-Learning group, in view that they need to develop an “e-Learning module on Toys” [4]. This was successfully developed and launched by PROSAFE in the respective e-Learning portal that can be found within the PROSAFE website - www.prosafe.org.

The Risk Assessment group within JA2013 also liaised with this working group to initially assist this working group in developing basic risk assessment templates on toys. In turn, this working group on toys (JA2013), through experience gathered through this project, was able to give back valid input to this Risk Assessment group and today, templates on risk assessment of toys, intended for children under 3 years of age, can be found within the respective PROSAFE webpage link:
http://www.prosafe.org/index.php?option=com_content&view=article&id=78&Itemid=424

It is envisaged that this Final Technical Report which will soon be published in the PROSAFE website and will therefore serve to further create additional liaison and discussions in the area of toy safety.

6 Evaluation, Lessons Learned

Looking back at this two-year activity, there are some lessons which could be derived from this project.

At a technical level;

- ✓ One needs to be careful how to interpret data and statistics. Market surveillance authorities, in order to be more efficient, will continue to zoom in on those products which are possibly non-compliant. Therefore, any statistics need to be evaluated with certain caution.
- ✓ It is clear that the market surveillance authorities are still able to find considerable non-compliances and risks in the area of “small parts” as described in clause 5.1 of EN71-1:2011+A3:2014. This was also evident in the previous joint action on such similar toys, coordinated by PROSAFE during 2009- 2010. More coordinated effort between surveillance authorities and economic operators may be needed in this area to try to further improve the level of safety.
- ✓ More coordination may be needed with Customs to focus more on products with no label information about the responsible economic operator (manufacturer / importer). Out of the 265 tested for mechanical requirements, 33 fell in this category and it resulted that 76% of them did not comply with the respective mechanical requirements.
- ✓ Warnings, markings and instructions for use need to be given more importance by economic operators since there were several non-compliances in this area. These are particularly important to consumers.
- ✓ In the case of DIBP, this is probably the first time that market surveillance authorities have tested for this chemical and also took action accordingly. However, more scientific information may be needed in this area to better determine the risk associated with certain levels of this chemical. It is clear that toys with more than 5% DIBP are not compliant with the Toy Safety Directive 2009/48/EC. However, the CLP regulation specifies even lower limits. Further research may be needed to determine exactly the limit which could cause a particular risk to a child in the case of DIBP so that market surveillance authorities can act accordingly.
- ✓ There were no particular issues or problems related to the testing of samples in line with the respective standards focused upon.
- ✓ Test reports showing individual pictures of each non-compliance found, together with an explanation from the laboratory, was found to be useful for market surveillance authorities, in particular when performing risk assessment.
- ✓ The checklists and internal guidance document used for this activity helped to zoom effectively on samples which showed possible non-compliances in particular for toys intended for children under three years of age.
- ✓ Input from stakeholders during the meetings, including in particular technical input due to their expertise and experiences, proved to be useful to the whole group, ensuring that the activity is more focused.

At an administrative level;

- ✓ Joint tendering for testing of samples continued to show that it is very advantageous for market surveillance authorities since larger amounts of samples tested meant better test prices for surveillance authorities. This also meant that these working group could perform higher numbers of tests and focusing on a much larger number of samples.
- ✓ The involvement of the TOY-ADCO group, in particular, in the development of a priority list for future joint actions, has proved to be quite positive. The result is that more market surveillance authorities are able to participate in these future joint actions since they are taking into account what their needs are and focusing on toy product groups which are of particular interest to them.

7 Bibliography

1. “Grant Agreement for an Action - Multiple Beneficiaries, Agreement Number 2011 82 01”. Grant Agreement 2011 82 01 - GPSD JA.
2. Guidance Document on the interpretation of the concept “which can be placed in the mouth” as laid down in the Annex to the 22nd amendment of Council Directive 76/769/EEC. This may be found at the following link: http://ec.europa.eu/growth/sectors/toys/safety/guidance/index_en.htm
3. “Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System ‘RAPEX’ established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive)”. Published in the Official Journal of the European Union L22/1.
4. “e-learning module on Toys” - A working group within JA2013 had the objective to develop an e-Learning module on Toys. Various other e-Learning modules have been developed over time, including one on risk assessment. This e-Learning module on toys was successfully finalised by end of 2014. The e-Learning module may be freely accessed by clicking on the “e-Learning portal” link found within the main PROSAFE website - www.prosafe.org.

All standards can be obtained from the national standardisation bodies if nothing else is stated. An overview of these bodies can be found on the website of the European Committee for Standardisation, CEN at www.cen.eu.